MEDICAID DRUG REBATE OPERATIONAL TRAINING GUIDE

Prepared by HCFA's Medicaid Bureau Drug Rebate Staff

OCTOBER 1996

HCFA
MEDICARE • MEDICAID
Health Care Financing Administration

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OF

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INTRODUCTION

INTRODUCTION

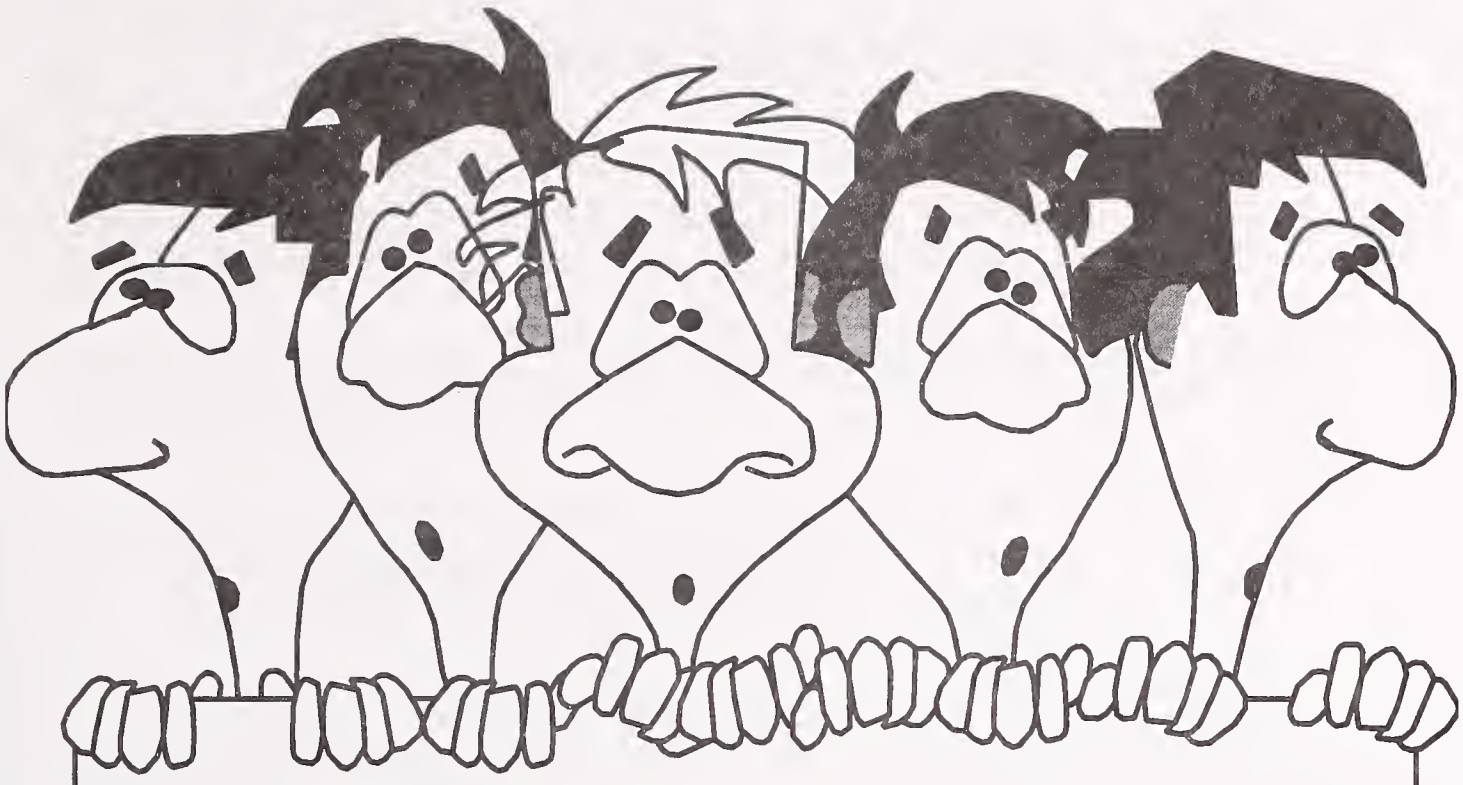
This guide was developed for use by State and drug labeler personnel responsible for activities relating to the Medicaid Drug Rebate Program, e.g., calculating and reporting drug pricing data, preparing invoices, reporting utilization data, receiving and reconciling invoices, quarterly drug rebate payments, and dispute resolution. The guide provides a quick, easy reference source to assist in the operation of the drug rebate program by simplifying complex processes and converting statutory language into plain words. For the purpose of this guide, the term "labeler" is used to refer to manufacturers, repackagers, and relabelers.

Guide Format

- **Individual Sections** - Topical sections are provided for quick and easy reference. In addition to sections relating to statutory and program operational requirements, sections are provided for such items as program definitions, index, acronyms, and a HCFA Drug Rebate Directory.

- **Binder construction** - The use of binders provides the best method to insert or delete guide material when necessary, easily copy the guide, or distribute guide sections among those responsible for various activities in the program. HCFA will distribute additions and/or replacement pages to the guide, as needed.

- **Cross referencing** - Many sections of the guide purposely contain information found in other sections. Although it may seem repetitive, it is done to provide the least frustration when researching a particular subject matter that overlaps another or requires the use of forms.



PROGRAM

ORIENTATION

PROGRAM ORIENTATION

The Department of Health and Human Services, Health Care Financing Administration (HCFA) is responsible for administering the Federal Medicaid program (title XIX of the Social Security Act (the Act)).

For the purpose of this guide, there are three pieces of legislation which affect title XIX of the Act:

The Omnibus Budget Reconciliation Act of 1990
The Veterans Health Care Act of 1992
The Omnibus Budget Reconciliation Act of 1993

THE OMNIBUS BUDGET RECONCILIATION ACT OF 1990, section 4401, amended title XIX of the Act by adding section 1927 which requires rebate agreements for covered outpatient drugs, better known as the Medicaid Drug Rebate Program.

Section 1927 of the Act, **effective January 1, 1991**, sets forth the requirements of the Medicaid Drug Rebate Program. In general, in order for Federal Medicaid matching funds to be available to States for covered outpatient drugs of a labeler, the labeler must enter into and have in effect a rebate agreement with the Federal government. Without an agreement in place, States can not receive Federal funding for outpatient drugs dispensed to Medicaid recipients. Rebate amounts received by States are considered a reduction in the amount expended by States for medical assistance for purposes of Federal matching funds under the Medicaid program.

A rebate agreement requires the labeler to provide to each State a quarterly rebate for covered outpatient drugs of the labeler paid for by the State during the quarter. The agreement also requires the labeler to provide pricing information to HCFA. This information consists of the average manufacturer price (AMP) and the labeler's best price (BP) for covered outpatient drugs for each quarter. In turn, the labeler receives information from the States on the total number of dosage units of each covered outpatient drug paid for during the quarter. The labeler remits to the State a rebate payment based on the number of units paid for and the unit rebate amount (URA). The URA is calculated using the AMP v. BP formula set forth in section 1927 of the Act and detailed in Section H of this guide.

THE VETERANS HEALTH CARE ACT OF 1992 (VHCA) was enacted on November 4, 1992, and amended section 1927(a) of the Act. The effects of the VHCA of 1992 relate to coverage of labelers' drugs, duplicate payments, rebate calculations, and Best Price (BP). Specifically, the VHCA:

1. Requires all labelers to enter into a drug pricing agreement with the Public Health Service (PHS), and that labelers of single source and innovator multiple source drugs, biologicals, or insulin enter into a master agreement with the Department of Veterans Affairs, in order to continue receiving Medicaid coverage of their products.

2. Prevents a labeler from paying a Medicaid rebate on discounted drugs sold to PHS covered entities.

3. Increases the rebate calculation for single source and innovator multiple source drugs to 15.7% of AMP through December 1993, and removes the 50% CAP of AMP beginning 1/1/93.

4. Requires labelers to exclude from BP any prices charged to specific entities (see pricing data definitions in Section F of this guide for a list of the entities involved).

The detailed effects of the VHCA are discussed throughout this guide in their respective section(s).

THE OMNIBUS BUDGET RECONCILIATION ACT OF 1993 was enacted by the Congress on August 10, 1993, and became effective on October 1, 1993. This legislation effected major changes to the Medicaid Drug Rebate Program regarding single-source and innovator multiple-source drugs approved by the Food and Drug Administration (FDA) after October 1, 1990. Specifically, the legislative change affects the Baseline AMP and the Baseline Consumer Price Index-Urban (CPI-U), which ultimately impacts on the computation of the URA. (Baseline AMP, Baseline CPI-U, and the URA computation are discussed in Sections F and H of this guide.)

..IN THE BEGINNING...

When the Drug Rebate Program was starting up in 1991, a list of several thousand drug companies, along with names and addresses, was acquired by HCFA from the FDA. HCFA conducted a mass mailing in an attempt to contact all, or at least the vast majority, of drug manufacturers, repackagers, relabelers, and any other entities that may need to enter into this new program in order to continue to have their products covered in the State Medicaid Programs. There were over 1,000 packages sent out with a letter explaining what the program was about and why they should sign and return the contract. Also, included was a HCFA "Hotline" phone number by which we would answer questions about the program and what it meant to sign the agreement. Due to the limited volume of calls received after the fourth year of the program, the "Hotline" was discontinued in 1995 at the time of HCFA's physical move to a single site location. In its place, HCFA distributed to all labelers and States a list of Drug Rebate Team members, their phone numbers, and their primary responsibilities.

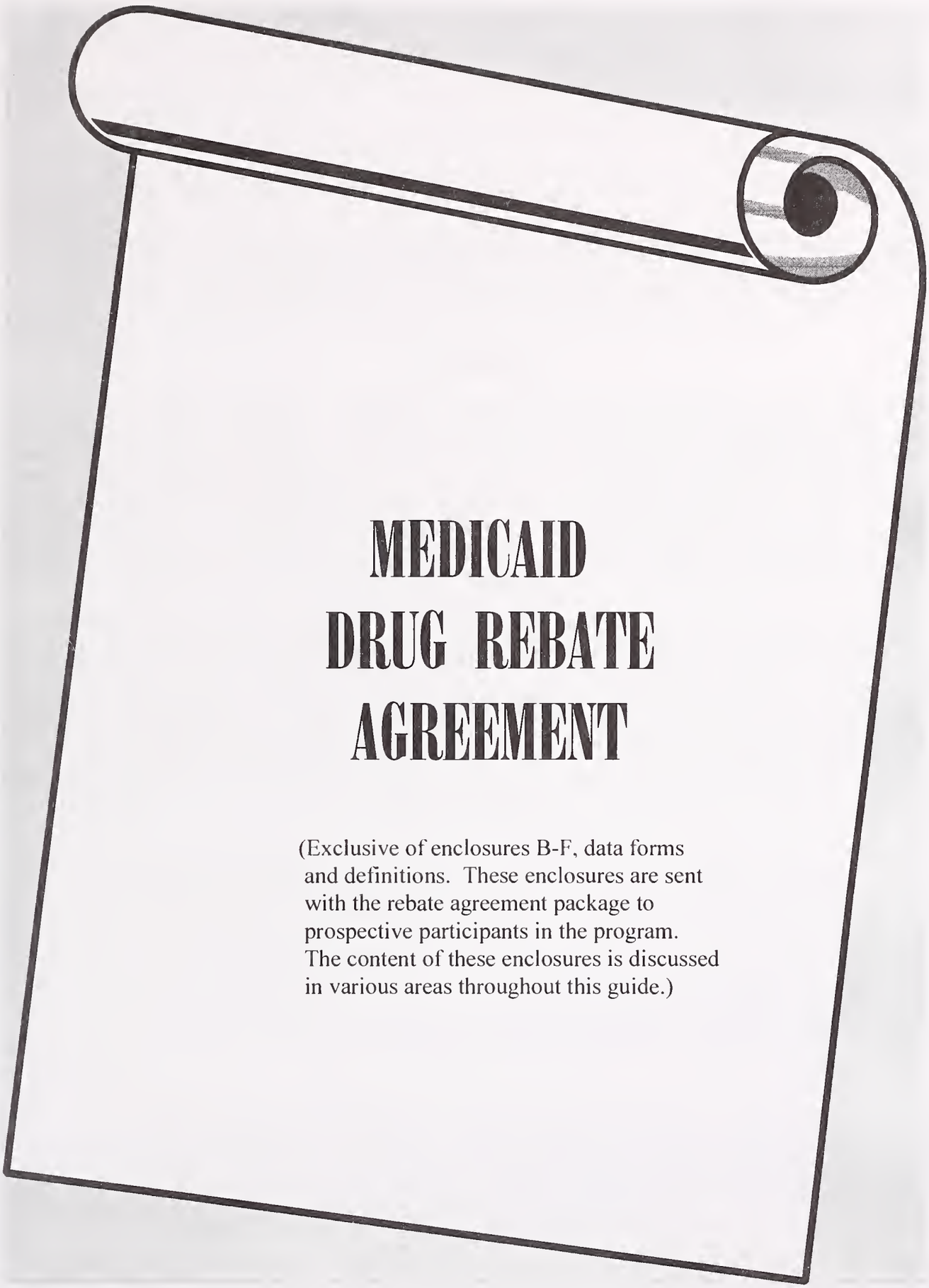
Originally, there were about 250 responses from HCFA's mailing, mostly from the larger companies, a few of which were already somewhat familiar with the program. By the time the program really got rolling, we were into the second half of 1991 and had successfully included about 340 companies in the original group.

..TODAY...

There are approximately 500 labelers participating in the Medicaid Drug Rebate Program. Drug companies now just starting up, or currently established companies that now wish to be included in the Drug Rebate Program, will generally get in touch with HCFA's Drug Rebate Team through contacts at State agencies or pharmacies. The first thing new companies must do after receiving the Drug Rebate Agreement package from HCFA is to complete the signature page of the agreement (see Section C of this guide), fill out all contact information attached to the agreement, and send both items to the address provided in HCFA's cover letter. After HCFA receives the completed contract and attachments, the

drug company will be established on HCFA's drug rebate data base and a letter of acceptance will be sent to the company along with the start date of their participation in the program.

The start date depends on the date of receipt by HCFA of the signed rebate agreement. Generally, a company's start date is the first day of the first quarter that falls more than 60 days from the postmark of their signed agreement. For example, an agreement postmarked on April 30 will result in a start date of July 1. A postmark, however, of May 8 will delay the start date until the quarter beginning October 1.



MEDICAID DRUG REBATE AGREEMENT

(Exclusive of enclosures B-F, data forms and definitions. These enclosures are sent with the rebate agreement package to prospective participants in the program. The content of these enclosures is discussed in various areas throughout this guide.)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care Financing Administration

6325 Security Boulevard
Baltimore, MD 21207

FEB 14 1991

Dear Manufacturer:

Enclosed with this cover note you will find an agreement (enclosure A) for your signature and related documents (enclosures B-F). As discussed, your signature is required in order for payment to be made under the Medicaid program for prescription drugs.

BACKGROUND

Section 4401 of the Omnibus Budget Reconciliation Act of 1990 (Public Law 101-508), enacted November 5, 1990, requires a drug manufacturer to enter into and have in effect a rebate agreement with the Federal government for States to receive funding for drugs dispensed to Medicaid recipients. For purposes of this legislation, you are considered a drug manufacturer if you hold legal title to the National Drug Code (NDC) number for a prescription drug, non-prescription drug or biological product.

In order for payment to be made under Medicaid, you must complete and sign this agreement, fill in the information on the related documents, and return them to the Health Care Financing Administration (HCFA). Under the terms of the agreement, you must supply information within 30 days after the end of each calendar quarter on the average manufacturer price (or AMP) of your drugs and, for some drugs, the best price at which they were sold. The definitions of AMP and best price are given in the rebate agreement.

States will then report to you, within 60 days after the end of each calendar quarter, the quantity of your drugs dispensed and for which they made Medicaid payment. Within 30 days of receipt of this information, you must rebate a portion of the price you received from the sale of your drugs which were paid for by these State Medicaid Agencies. This portion varies depending on whether the drug is considered to be a single source drug, innovator multiple source drug, or noninnovator multiple source drug. The definitions of these types of drugs can also be found in the rebate agreement.

If you choose to participate in this program, State Medicaid programs are required to cover your drugs with the exception of certain drugs cited in 1927(d)(1) and (2) of the Social Security Act (the Act). If you choose not to participate, States cannot receive Federal Medicaid funding for your drugs.

The law was effective January 1, 1991. Agreements entered into before March 1, 1991 will be retroactive to January 1, 1991. Agreements entered into on or after March 1 will not be effective

until the calendar quarter that begins more than 60 days after the agreement is entered into. Therefore, if you enter into an agreement on or after March 1, the earliest date that your drugs may be covered is July 1, 1991 (i.e., your drugs are not covered from January 1, 1991-June 30, 1991). This date may be later depending on the actual date after March 1 that you enter into an agreement. The date an agreement is entered into will be the date of the Post Office's postmark on the envelope for the returned agreement.

REBATE CALCULATION

Section 1927(c) of the Act specifies the amount of the rebate that you are required to pay the State Medicaid Agency if you participate in the program. Generally, the rebate amount will be calculated as follows. (The definitions of the terms used here are contained in the agreement).

Calendar Year (CY) 1991

Single source/innovator multiple source drugs
The greater of:
12.5% of AMP
OR
AMP minus best price
(The rebate is capped at 25% of AMP.)

An additional rebate must be paid on a drug-by-drug basis in the amount by which the increase in the AMP exceeds the increase in the Consumer Price Index-Urban (CPI-U) from October 1, 1990 to the month before the calendar quarter of the rebate.

Noninnovator multiple source drugs
10% of AMP

CY 1992

Single source/innovator multiple source drugs
The greater of:
12.5% of AMP
OR
AMP minus best price
(The rebate is capped at 50% of AMP.)

An additional rebate must be paid on a drug-by-drug basis in the amount by which the increase in the AMP exceeds the increase in the Consumer Price Index-Urban (CPI-U) from October 1, 1990 to the month before the calendar quarter of the rebate.

Noninnovator multiple source drugs
10% of AMP

CY 1993

Single source/innovator multiple source drugs
The greater of:
15% of AMP
OR
AMP minus best price
(The rebate is not capped.)

An additional rebate must be paid on a drug-by-drug basis in the amount by which the increase in the AMP exceeds the increase in the Consumer Price Index-Urban (CPI-U) from October 1, 1990 to the month before the calendar quarter of the rebate.

Noninnovator multiple source drugs
10% of AMP

CY 1994 and thereafter

Single source/innovator multiple source drugs
The greater of:
15% of AMP
OR
AMP minus best price
(The rebate is not capped.)

An additional rebate must be paid on the weighted basis in an amount by which the increase in the AMP exceeds the increase in the Consumer Price Index-Urban (CPI-U) from October 1, 1990 to the month before the calendar quarter of the rebate.

Noninnovator multiple source drugs
11% of AMP

DATA SYSTEMS REQUIREMENTS

Enclosures B-E provide information on the data systems requirements for your participation in the program.

1. Enclosure B entitled, "Supplemental Data Sheet", must be completed and returned with the signed rebate agreement. Included in this enclosure are questions for persons to contact, their addresses, and three data transmission options, one of which must be selected as your method of sending your drug product information to HCFA. This requested information

will enable us to direct program memoranda, data specifications, error inquiries and informational materials to the proper addresses and individuals within your organization. This enclosure must be completed and returned for each labeler code portion of the NDC number issued to your company by the Food and Drug Administration.

Subsequent to this initial submittal, changes to contact names, addresses and telephone numbers should be submitted to HCFA as they occur. This information should be submitted on letterhead stationery, signed by your authorized representative and forwarded to the HCFA address under the "Completing the Rebate" section of this cover letter.

2. Enclosure C entitled, "Manufacturers Data Definitions", contains the definitions of the data elements that are required for each of your drugs identified by an NDC number. Included in this enclosure is the format to be used for paper submittals and the record layout for telecommunications. Detailed specifications for telecommunications or diskette will be sent to your organization as soon as we process your signed agreement containing the data submittal option chosen by your organization. If you do not have the capability to submit the required information on diskette or telecommunications and have 5 or fewer drug products you will be allowed to submit paper documentation for the first 2 quarters covered by the rebate agreement. If you are in this category please make arrangements for conversion to diskette or telecommunications at your earliest opportunity.

3. Enclosure D, entitled "Medicaid Drug Rebate Data Elements Records from HCFA to State Agencies Quarterly", lists those data elements which will be sent to the States by HCFA.

4. Enclosure E, entitled "Medicaid Drug Data Elements Record from State Agencies to HCFA and Manufacturers Quarterly", describes those data elements which must be sent by the States to manufacturers and to HCFA for each drug product identified by an NDC number.

STATE REQUIREMENTS

Because the rebate agreement is between HCFA and the manufacturers, it does not address a number of requirements that the State Medicaid programs must meet or how HCFA plans to implement these requirements.

It will be important that State Medicaid programs maintain a database by manufacturer to reliably produce data on the quantity of the drugs dispensed and for which payment was made. HCFA will monitor that performance and where problems are noted (including those brought to our attention by you), will work to bring the State(s) into compliance with these requirements.

The validity of the Medicaid utilization information is also of importance to HCFA. We have required that State Medicaid Agencies report their utilization data by full NDC number, except where States do not have such a capability. Where a State does not currently have the capability to provide full NDC numbers, we will mandate that it use full numbers starting March 1, 1992. We are also seriously considering requiring States to report their claims paid by ZIP code (or if unable to do so, to provide a claims history file) starting no later than March 1, 1993.

State Medicaid Agencies will receive information on the "unit rebate amount" from HCFA. This will tell them what rebate amount to expect from you per unit (tablet, gram, ml, etc.) of drug. Some States may use this to generate an invoice of the total rebate expected from you. For single source and innovator multiple source drugs, the unit rebate amount will include any additional rebate due because the average manufacturer price increase of the drugs exceeded the CPI-U.

Finally, HCFA will monitor the timeliness of the rebate payments through the States. Late manufacturer rebate payments received by the State will be noted and actions, as provided by the Act, taken by HCFA.

COMPLETING THE REBATE AGREEMENT

Please note this is a standard rebate agreement being offered to all manufacturers. You may not alter it, modify it, or otherwise change it. I have signed this agreement on behalf of HCFA. The agreement that is part of this package must be the one that is signed by you and returned. If these conditions are not met, we will return the agreement to you and request that you meet these conditions. The date that the rebate agreement is entered into will be the date of the postmark for the agreement returned to us properly completed and executed.

Following this cover note is additional information presented in a question and answer format (enclosure F).

HCFA has also established a hotline telephone number if you have further questions or if you would like the CPI-U numbers. That number is (301) 966-3249 and will be open 8:00 a.m.-5:00 p.m. Monday-Friday except Federal holidays.

Signed rebate agreements should be returned to the following address:

Health Care Financing Administration
Medicaid Bureau
Post Office Box 26686
Baltimore, Maryland 21207-0486

Please do not send certified or registered mail or express packages to this address as they will be rejected. If you wish to confirm receipt by us of the rebate agreement, please enclose a self addressed postcard with it. We will date stamp the postcard and return it to you upon receipt of the agreement.

This cover note is meant to give you only a brief overview of the law and of the rebate agreement and does not contain a complete description of the Medicaid drug rebate requirements. It is also not a part of the rebate agreement. Before you choose to participate, please read the rebate agreement and other enclosures to this letter in their entirety.

I would again stress that if you wish to have your drugs or biologicals eligible for Federal Medicaid funding before July 1, 1991, you must sign this agreement and have it postmarked by February 28, 1991.

I realize that the timeframes for implementing this program are short. Accordingly, I have tried to identify and resolve as many issues for you as I could. I look forward to working with you in the operation of this program.

Sincerely,

Christine Nye
Director
Medicaid Bureau
Health Care Financing
Administration

Enclosure A: Rebate Agreement
Enclosure B: Supplemental Data Sheet
Enclosure C: Manufacturer Data Definitions
Enclosure D: Medicaid Drug Rebate Data Elements Records from HCFA to State Agencies Quarterly
Enclosure E: Medicaid Drug Rebate Data Elements Records from HCFA to State Agencies Quarterly
Enclosure F: Questions and Answers

Enclosure A

REBATE AGREEMENT
Between
The Secretary of Health and Human Services
(hereinafter referred to as "the Secretary")
and
The Manufacturer Identified in Section XI of this Agreement
(hereinafter referred to as "the Manufacturer")

The Secretary, on behalf of the Department of Health and Human Services and all States and the District of Columbia (except to the extent that they have in force an Individual State Agreement) which have a Medicaid State Plan approved under 42 U.S.C. section 1396a, and the Manufacturer, on its own behalf, for purposes of section 4401 of the Omnibus Budget Reconciliation Act of 1990, Pub. L. No. 101-508, and section 1927 of the Social Security Act (hereinafter referred to as "the Act"), 42 U.S.C. 1396s, hereby agree to the following:

I DEFINITIONS

The terms defined in this section will, for the purposes of this agreement, have the meanings specified in section 1927 of the Act as interpreted and applied herein:

(a)"Average Manufacturer Price (AMP)" means, with respect to a Covered Outpatient Drug of the Manufacturer for a calendar quarter, the average unit price paid to the Manufacturer for the drug in the States by wholesalers for drugs distributed to the retail pharmacy class of trade (excluding direct sales to hospitals, health maintenance organizations and to wholesalers where the drug is relabeled under that distributor's national drug code number). Federal Supply Schedule prices are not included in the calculation of AMP. AMP includes cash discounts allowed and all other price reductions (other than rebates under section 1927 of the Act), which reduce the actual price paid. It is calculated as a weighted average of prices for all the Manufacturer's package sizes for each Covered Outpatient Drug sold by the Manufacturer during that quarter. Specifically, it is calculated as Net Sales divided by numbers of units sold, excluding free goods (i.e. drugs or any other items given away, but not contingent on any purchase requirements). For Bundled Sales, the allocation of the discount is made proportionately to the dollar value of the units of each drug sold under the bundled arrangement. The Average Manufacturer Price for a quarter must be adjusted by the Manufacturer if

cumulative discounts or other arrangements subsequently adjust the prices actually realized.

(b)"Base Consumer Price Index-Urban (CPI-U)"is the CPI-U for September, 1990. For drugs approved by FDA after October 1, 1990, "Base CPI-U" means the CPI-U for the month before the month in which the drug was first marketed.

(c)"Base Date AMP" means the AMP for the 7/1/90-9/30/90 quarter for purposes of computing the AMP as of 10/1/90. For drugs approved by FDA after October 1, 1990, "Base Date AMP" means the AMP for the first day of the first month in which the drug was marketed. In order to meet this definition, the drug must have been marketed on that first day. If the drug was not marketed on that first day, "Base Date" means the AMP for the first day of the month in which the product was marketed for a full month.

(d)"Best Price" means, with respect to Single Source and Innovator Multiple Source Drugs, the lowest price at which the manufacturer sells the Covered Outpatient Drug to any purchaser in the United States in any pricing structure (including capitated payments), in the same quarter for which the AMP is computed. Best price includes prices to wholesalers, retailers, nonprofit entities, or governmental entities within the States (excluding Depot Prices and Single Award Contract Prices of any agency of the Federal Government). Federal Supply Schedule prices are included in the calculation of the best price.

The best prices shall be inclusive of cash discounts, free goods, volume discounts, and rebates, (other than rebates under Section 1927 of the Act).

It shall be determined on a unit basis without regard to special packaging, labeling or identifiers on the dosage form or product or package, and shall not take into account prices that are Nominal in amount. For Bundled Sales, the allocation of the discount is made proportionately to the dollar value of the units of each drug sold under the bundled arrangement. The best price for a quarter shall be adjusted by the Manufacturer if cumulative discounts, rebates or other arrangements subsequently adjust the prices actually realized.

(e)"Bundled Sale" refers to the packaging of drugs of different types where the condition of rebate or discount is that more than one drug type is purchased, or where the resulting discount or rebate is greater than that which would have been received had the drug products been purchased separately.

(f)"Consumer Price Index-Urban (CPI-U)" means the index of consumer prices developed and updated by the U.S. Department of Commerce. As referenced in section 1927(c) of the Act, it is the CPI for all urban consumers (U.S. Average) and, except for the base CPI-U, it

shall be the index for the month before the beginning of the calendar quarter for which the rebate is made.

(g)"Covered Outpatient Drug" will have the meaning as set forth in Section 1927(k)(2),(k)(3) and (k)(4) of the Act, and with respect to the Manufacturer includes all such drug products meeting this definition. For purposes of coverage under this agreement, all of those Covered Outpatient Drugs are identified by the Manufacturer's labeler code segment of the NDC number. Certain Covered Outpatient Drugs, such as specified by Section 1927 (d)(1)-(3) of the Act, may be restricted or excluded from Medicaid payment at State option but shall be included by the Manufacturer for purposes of this agreement.

(h)"Depot Price" means the price(s) available to any depot of the federal government, for purchase of drugs from the Manufacturer through the depot system of procurement.

(i)"Health Care Financing Administration (HCFA)" means the agency of the Department of Health and Human Services having the delegated authority to operate the Medicaid Program.

(j)"Individual State Agreement" means an agreement between a State and a Manufacturer authorized or approved by HCFA as meeting the requirements specified in Section 1927(a)(1) or (a)(4) of the Act. Amendments or other changes to agreements under 1927(a)(4) shall not be included in this definition unless specifically accepted by HCFA.

An existing agreement that met these requirements as of the date of enactment of P.L. No. 101-508 (November 5, 1990), can be modified to give a greater rebate percentage.

(k)"Innovator Multiple Source Drug" will have the meaning set forth in Section 1927(k)(7)(A)(ii) of the Act and shall include all Covered Outpatient Drugs approved under a New Drug Application (NDA), Product License Approval (PLA), Establishment License Approval (ELA) or Antibiotic Drug Approval (ADA). A Covered Outpatient Drug marketed by a cross-licensed producer or distributor under the approved NDA shall be included as an innovator multiple source drug when the drug product meets this definition.

(l)"Manufacturer" will have the meaning set forth in Section 1927(k)(5) of the Act except, for purposes of this agreement, it shall also mean the entity holding legal title to or possession of the NDC number for the Covered Outpatient Drug.

(m) "Marketed" means that a drug was first sold by a manufacturer in the States after FDA approval.

(n)"Medicaid Utilization Information" means the information on the total number of units of each dosage form and strength of the Manufacturer's Covered Outpatient Drugs reimbursed during a quarter under a Medicaid State Plan. This information is based on claims paid by the State Medicaid Agency during a calendar quarter and not drugs that were dispensed during a calendar quarter (except it shall not include drugs dispensed prior to January 1, 1991). The Medicaid Utilization Information to be supplied includes: 1) NDC number; 2) Product name; 3) Units paid for during the quarter by NDC number; 4) Total number of prescriptions paid for during the quarter by NDC number; and 5) Total amount paid during the quarter by NDC number. A State may, at its option, compute the total rebate anticipated, based on its own records, but it shall remain the responsibility of the manufacturer to correctly calculate the rebate amount based on its correct determination of AMP and, where applicable, Best Price.

(o)"National Drug Code (NDC)" is the identifying drug number maintained by the Food and Drug Administration (FDA). For the purposes of this agreement the complete 11 digit NDC number will be used including labeler code (which is assigned by the FDA and identifies the establishment), product code (which identifies the specific product or formulation), and package size code. For the purposes of making Rebate Payments, Manufacturers must accept the NDC number without package size code from States that do not maintain their records by complete NDC number.

(p) "Net Sales" means quarterly gross sales revenue less cash discounts allowed and all other price reductions (other than rebates under section 1927 of the Act) which reduce the actual price paid; and as further defined under the definition of AMP.

(q)"New Drug" means a Covered Outpatient Drug approved as a new drug under section 201(p) of the Federal Food, Drug, and Cosmetic Act.

(r)"New Drug Coverage" begins with the date of FDA approval of the NDA, PLA, ELA or ADA, for a period of six months from that date, with the exception of drugs not under the rebate agreement or classes of drugs States elect to exclude.

(s)"Nominal Price", for purposes of excluding prices from the Best Price calculation, means any price less than 10% of the AMP in the same quarter for which the AMP is computed.

(t)"Noninnovator Multiple Source Drug" shall have the meaning as set forth in Section 1927(k)(7)(A)(iii) of the Act. It also includes Covered Outpatient Drugs approved under an ANDA or AADA.

(u)"Quarter" means calendar quarter unless otherwise specified.

(v)"Rebate Payment" means, with respect to the Manufacturer's Covered Outpatient Drugs, the quarterly payment by the Manufacturer to the State Medicaid Agency, calculated in accordance with section 1927 of the Act and the provisions of this agreement. The terms "Base CPI-U" and "Base Date AMP" will be applicable to the calculations under 1927(c).

(w)"Secretary" means the Secretary of the United States Department of Health and Human Services, or any successor thereto, or any officer or employee of the Department of Health and Human Services or successor agency to whom the authority to implement this agreement has been delegated.

(x) "Single-Award Contract" means a contract between the Federal Government and a Manufacturer resulting in a single supplier for a Covered Outpatient Drug within a class of drugs. The Federal Supply Schedule is not included in this definition as a single-award contract.

(y)"Single-Award Contract Price" means a price established under a Single-Award Contract.

(z)"Single Source Drug" will have the meaning set forth in Section 1927(k)(7)(A)(iv) of the Act. It also includes a Covered Outpatient Drug approved under a PLA, ELA or ABA.

(aa)"States" means the 50 states and the District of Columbia.

(bb)"State Medicaid Agency" means the agency designated by a State under Section 1902(a)(5) of the Act to administer or supervise the administration of the Medicaid program.

(cc)"Unit" means drug unit in the lowest identifiable amount (e.g. tablet or capsule for solid dosage forms, milliliter for liquid forms, gram for ointments or creams). The Manufacturer will specify the unit associated with each Covered Outpatient Drug, as part of the submission of data, in accordance with the Secretary's instructions provided pursuant to Appendix A.

(dd)"Unit Rebate Amount" means the unit amount computed by the Health Care Financing Administration to which the Medicaid utilization information may be applied by States in invoicing the Manufacturer for the rebate payment due.

(ee)"Wholesaler" means any entity (including a pharmacy or chain of pharmacies) to which the manufacturer sells the Covered Outpatient Drug, but that does not relabel or repackage the Covered Outpatient Drug.

II MANUFACTURER'S RESPONSIBILITIES

In order for the Secretary to authorize that a State receive payment for the Manufacturer's drugs under Title XIX of the Act, 42 U.S.C. Section 1396 et seq., the Manufacturer agrees to the following:

(a) To calculate and, except as provided under section V(b) of this agreement, to make a Rebate Payment to each State Medicaid Agency for the Manufacturer's Covered Outpatient Drugs paid for by the State Medicaid Agency during a quarter.

A separate listing of all Covered Outpatient Drugs and other information, in accordance with HCFA's specifications pursuant to Appendix A, must be submitted within 30 calendar days of entering into this agreement and be updated quarterly. The Manufacturer's quarterly report is to include all new NDC numbers and continue to list those NDC numbers for drugs no longer marketed.

(b) Except as provided under V(b), to make such rebate payments for each calendar quarter within 30 days after receiving from the State the Medicaid Utilization Information defined in this agreement. Although a specific amount of information has been defined in I(n) of this agreement, the Manufacturer is responsible for timely payment of the rebate within 30 days of receiving, at a minimum, information on the number of units paid, by NDC number.

(c) To comply with the conditions of 42 U.S.C. section 1396s, changes thereto and implementing regulations as the Secretary deems necessary and specifies by actual prior notice to the manufacturer.

(d) That rebate agreements between the Secretary and the Manufacturer entered into before March 1, 1991 are retroactive to January 1, 1991. Rebate agreements entered into on or after March 1, 1991 shall be effective the first day of the calendar quarter that begins more than 60 days after the date the agreement is entered into.

(e) To report to the Secretary, in accordance with specifications pursuant to Appendix A, that information on the Average Manufacturer Price and, in the case of Single Source and Innovator Multiple Source Drugs, the Manufacturer's Best Price for all Covered Outpatient Drugs. The Manufacturer agrees to provide such information within 30 days of the last day of each quarter beginning with (1) the January 1, 1991-March 31, 1991 quarter or (2) the quarter in which any subsequent effective date of this agreement lies. Other information in Appendix A shall also be required within 30 days of the last day of the quarter. Adjustments to AMP or Best Price for prior quarters shall also be reported on this quarterly basis.

(f) In the case of Single Source and Innovator Multiple Source drugs, to report to the Secretary, in a manner prescribed by the Secretary, the information in Appendix A on the Base Date AMP. The Manufacturer agrees to provide such information within 30 days of the date of signing this agreement.

(g) To directly notify the States of a New Drug's Coverage.

(h) To continue to make a Rebate Payment on all of its Covered Outpatient Drugs for as long as an agreement with the Secretary is in force and State Medicaid Utilization Information reports that payment was made for that drug, regardless of whether the Manufacturer continues to market that drug. If there are no sales by the Manufacturer during a quarter, the AMP and Best Price last reported continue to be used in calculating rebates.

(i) To keep records (written or electronic) of the data and any other material from which the calculations of AMP and Best Price were derived. In the absence of specific guidance in section 1927 of the Act, Federal regulations and the terms of this agreement, the Manufacturer may make reasonable assumptions in its calculations of AMP and Best Price, consistent with the intent of section 1927 of the Act, Federal regulations and the terms of this agreement. A record (written or electronic) outlining these assumptions must also be maintained.

III SECRETARY'S RESPONSIBILITIES

(a) The Secretary will use his best efforts to ensure that the State agency will report to the Manufacturer, within 60 days of the last day of each quarter, and in a manner prescribed by the Secretary, Medicaid Utilization Information paid for during the quarter.

(b) The Secretary may survey those Manufacturers and Wholesalers that directly distribute their covered outpatient drugs to verify manufacturer prices and may impose civil monetary penalties as provided in section 1927(b)(3)(B) of the Act and IV of this agreement.

(c) The Secretary may audit Manufacturer calculations of AMP and Best Price.

IV PENALTY PROVISIONS

(a)The Secretary may impose a civil monetary penalty under III(b), up to $100,000 for each item, on a wholesaler, manufacturer, or direct seller of a Covered Outpatient Drug, if a wholesaler, manufacturer or direct seller of a Covered Outpatient Drug refuses a request for information about charges or prices by the Secretary

in connection with a survey or knowingly provides false information. The provisions of section 1128A of the Act (other than subsection (a) (with respect to amounts of penalties or additional assessments) and (b)) shall apply as set forth in section 1927(b)(3)(B).

(b) The Secretary may impose a civil monetary penalty, in an amount not to exceed $100,000, for each item of false information as set forth in 1927(b)(3)(C)(ii).

(c) The Secretary may impose a civil monetary penalty for failure to provide timely information on AMP, Best Price or Base Date AMP. The amount of the penalty shall be increased by $10,000 for each day in which such information has not been provided, as set forth in 1927(b)(3)(C)(i).

V DISPUTE RESOLUTION -- MEDICAID UTILIZATION INFORMATION

(a) In the event that in any quarter a discrepancy in Medicaid Utilization Information is discovered by the Manufacturer, which the Manufacturer and the State in good faith are unable to resolve, the Manufacturer will provide written notice of the discrepancy, by NDC number, to the State Medicaid Agency prior to the due date in II(b).

(b) If the Manufacturer in good faith believes the State Medicaid Agency's Medicaid Utilization Information is erroneous, the Manufacturer shall pay the State Medicaid Agency that portion of the rebate amount claimed which is not disputed within the required due date in II(b). The balance due, if any, plus a reasonable rate of interest as set forth in section 1903(d)(5) of the Act, will be paid or credited by the Manufacturer or the State by the due date of the next quarterly payment in II(b) after resolution of the dispute.

(c) The State and the Manufacturer will use their best efforts to resolve the discrepancy within 60 days of receipt of such notification. In the event that the State and the Manufacturer are not able to resolve a discrepancy within 60 days, HCFA shall require the State to make available to the Manufacturer the State hearing mechanism available under the Medicaid Program (42 Code of Federal Regulations section 447.253 (c)).

(d) Nothing in this section shall preclude the right of the Manufacturer to audit the Medicaid Utilization Information reported (or required to be reported) by the State. The Secretary shall encourage the Manufacturer and the State to develop mutually beneficial audit procedures.

(e) Adjustments to Rebate Payments shall be made if information indicates that either Medicaid Utilization Information, AMP or Best Price were greater or less than the amount previously specified.

(f) The State hearing mechanism is not binding on the Secretary for purposes of his authority to implement the civil money penalty provisions of the statute or this agreement.

VI DISPUTE RESOLUTION -- PRESCRIPTION DRUGS ACCESS AND STATE SYSTEMS ISSUES

(a) A State's failure to comply with the drug access requirements of section 1927 of the Act shall be cause for the Manufacturer to notify HCFA and for HCFA to initiate compliance action against the State under section 1904 of the Act. A request for compliance action may also occur when the Manufacturer shows a pattern or history of inaccuracy in Medicaid Utilization Information.

(b) Such compliance action by HCFA will not relieve the Manufacturer from its obligation of making the Rebate Payment as provided in section 1927 of the Act and this agreement.

VII CONFIDENTIALITY PROVISIONS

(a) Pursuant to Section 1927(b)(3)(D) of the Act and this agreement, information disclosed by the Manufacturer in connection with this Agreement is confidential and, not withstanding other laws, will not be disclosed by the Secretary or State Medicaid Agency in a form which reveals the Manufacturer, or prices charged by the Manufacturer, except as necessary by the Secretary to carry out the provisions of section 1927 of the Act, and to permit review under section 1927 of the Act by the Comptroller General.

(b) The Manufacturer will hold State Medicaid Utilization Information confidential. If the Manufacturer audits this information or receives further information on such data, that information shall also be held confidential. Except where otherwise specified in the Act or agreement, the Manufacturer will observe State confidentiality statutes, regulations and other properly promulgated policy.

(c) Notwithstanding the nonrenewal or termination of this Agreement for any reason, these confidentiality provisions will remain in full force and effect.

VIII NONRENEWAL AND TERMINATION

(a) Unless otherwise terminated by either party pursuant to the terms of this Agreement, the Agreement shall be effective for an

initial period of one year beginning on the date specified in section II(d) of this agreement and shall be automatically renewed for additional successive terms of one year unless the Manufacturer gives written notice of intent not to renew the agreement at least 90 days before the end of the current period.

(b) The Manufacturer may terminate the agreement for any reason, and such termination shall become effective the later of the first day of the first calendar quarter beginning 60 days after the Manufacturer gives written notice requesting termination, or the ending date of the term of the agreement if notice has been given in accordance with VII(a).

(c) The Secretary may terminate the Agreement for violations of this agreement or other good cause upon 60 days prior written notice to the Manufacturer of the existence of such violation or other good cause. The Secretary shall provide, upon request, a Manufacturer with a hearing concerning such a termination, but such hearing shall not delay the effective date of the termination.

(d) If this rebate agreement is nonrenewed or terminated, the Manufacturer is prohibited from entering into another rebate agreement as provided in section 1927(b)(4)(C) of the Act until a period of one calendar quarter has elapsed from the effective date of the termination, unless the Secretary finds good cause for earlier reinstatement.

(e) Any nonrenewal or termination will not affect rebates due before the effective date of termination.

IX GENERAL PROVISIONS

(a) Any notice required to be given pursuant to the terms and provisions of this Agreement will be sent in writing.

Notice to the Secretary will be sent to:

Chief, Non-Institutional Payment Policy Branch
Office of Medicaid Policy, Medicaid Bureau
Post Office Box 26686
Baltimore, MD 21207-0486

Notices to HCFA concerning data transfer and information systems issues are to be sent to:

Chief, Program Quality and Evaluation Branch
Office of Medicaid Management, Medicaid Bureau
Post Office Box 26686
Baltimore, MD. 21207-0486

The HCFA address may be updated upon written notice to the Manufacturer.

Notice to the Manufacturer will be sent to the address as provided with this agreement and updated upon Manufacturer notification to HCFA at the address in this agreement.

(b) In the event of a transfer in ownership of the Manufacturer, this agreement is automatically assigned to the new owner subject to the conditions specified in section 1927 and this agreement.

(c) Nothing in this Agreement will be construed to require or authorize the commission of any act contrary to law. If any provision of this Agreement is found to be invalid by a court of law, this Agreement will be construed in all respects as if any invalid or unenforceable provision were eliminated, and without any effect on any other provision.

(d) Nothing in this Agreement shall be construed as a waiver or relinquishment of any legal rights of the Manufacturer or the Secretary under the Constitution, the Act, other federal laws, or State laws.

(e) The rebate agreement shall be construed in accordance with Federal common law and ambiguities shall be interpreted in the manner which best effectuates the statutory scheme.

(f) The terms "State Medicaid Agency" and "Manufacturer" incorporate any contractors which fulfill responsibilities pursuant to the agreement unless specifically provided for in the rebate agreement or specifically agreed to by an appropriate HCFA official.

(g) Except for the conditions specified in II(c) and IX(a), this Agreement will not be altered except by an amendment in writing signed by both parties. No person is authorized to alter or vary the terms unless the alteration appears by way of a written amendment, signed by duly appointed representatives of the Secretary and the Manufacturer.

(h) In the event that a due date falls on a weekend or Federal holiday, the report or other item will be due on the first business day following that weekend or Federal holiday.

X APPENDIX

Appendix A attached hereto is part of this agreement.

XI SIGNATURES

FOR THE SECRETARY OF HEALTH AND HUMAN SERVICES

By: _____

Title: Deputy Director, Medicaid Bureau
Health Care Financing Administration
Department of Health and Human Services

Date: 2-11-91

ACCEPTED FOR THE MANUFACTURER

I certify that I have made no alterations , amendments or other changes to this rebate agreement.

By: _____

Title: _____

Name of Manufacturer: _____

Manufacturer Address _____

_____

Manufacturer Labeler Code(s): _____

Date: _____

CONFIDENTIAL

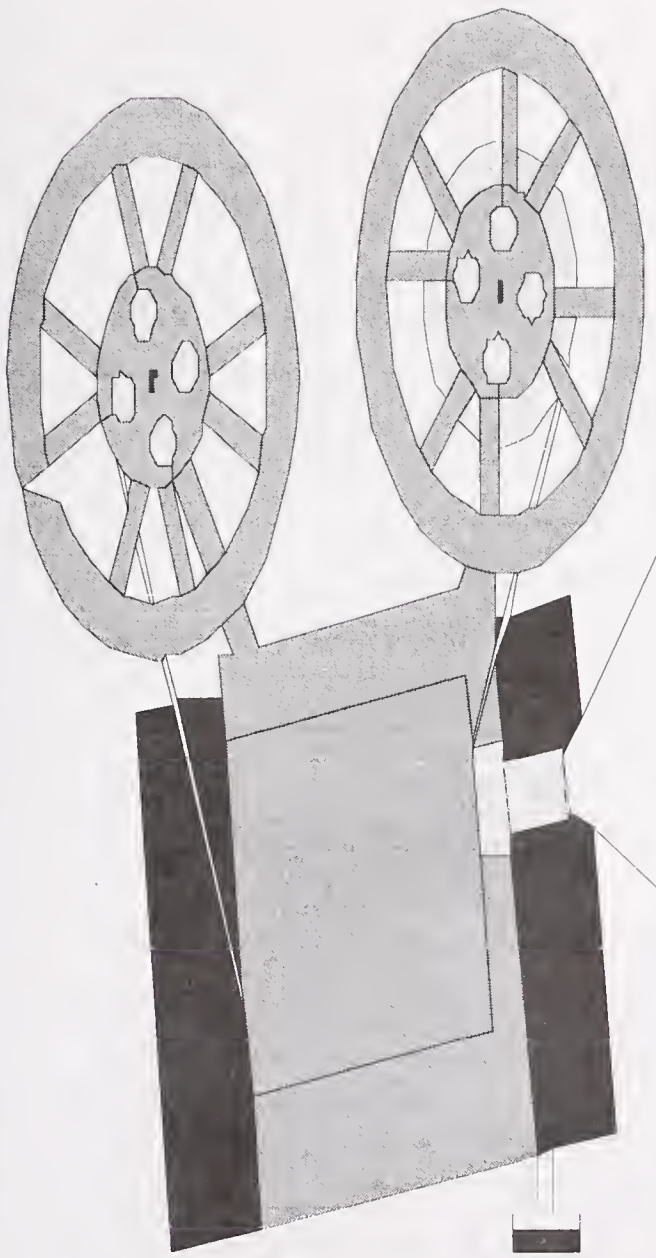
CONFIDENTIALITY

Section 1927(b)(3)(D) of the Act and the Medicaid Drug Rebate Agreement state that information disclosed by labelers is confidential and shall not be disclosed in a form which discloses the identity of a specific labeler, or prices charged by labelers. This provision covers all States as well as HCFA.

Although the statute provides for three exceptions to the disclosure of labeler/prices, data related to prices are subject to both privacy and trade secret restrictions and are **not released by HCFA and must not be released by States**. When pricing data is received by HCFA it is held in the strictest confidence and maintained only on HCFA's master files. HCFA sends URAs to States, but actual pricing data goes no farther than HCFA.

In instances where data is 1) public knowledge, 2) legally obtainable from other sources, or 3) are not considered confidential, HCFA complies with requests for data.

In accordance with the Drug Rebate Agreement, labelers will hold State Medicaid utilization information confidential. This includes additional information on original data received and any information acquired during audits of such data. Except where otherwise specified in the Act or the agreement, the labeler will observe State confidentiality statutes, regulations, and other properly promulgated policy.



PROGRAM

OVERVIEW

PROGRAM SYSTEM
AND
GENERAL REPORTING

This section describes the drug rebate program data system and gives a general outline of the flow of a quarterly rebate cycle, from labelers to HCFA, HCFA to States, States to labelers, and finally, labeler rebate payments to States.

HCFA's data system for the drug rebate program is called the Medicaid Drug Rebate Initiative (MDRI) master file. The general setup of the MDRI system begins with "Baseline" data generated by the labelers. This data consists of the "profile" of each product that has a National Drug Code (NDC) sent to HCFA using a specific record layout and containing specific data. DESI Indicator, Therapeutic Equivalency, Unit Type, and Drug Category are just a few examples of the data required to establish an NDC on the MDRI system. (See Section F for the detailed record layout and data elements required.)

Baseline data for all NDCs that can be dispensed as outpatient drugs is submitted initially within 30 days after the labeler is notified by HCFA that it has been accepted into the program. This notice also provides the labeler with their start date for participation in the program. From this point on, when submitting quarterly pricing data, a labeler **MUST** include Baseline data for every NDC that has a Market Date in the reporting quarter. For example, if a product is entering the market on 11-05-96, the Baseline data **MUST** be included in the 96-4 quarterly pricing data submission, due to HCFA before the end of January, 1997.

Once a labeler is participating in the program, current quarter pricing data, along with prior quarter updates and additions, (form HCFA-367) are due to HCFA within 30 days after the end of a calendar quarter.

HCFA processes the quarterly data and sends edit reports to labelers for data rejected by the system. If labelers can correct information shown on the edit report and return the data to HCFA before the system is shut down for rebate calculations, the corrected data will be entered and included in that quarter's unit rebate calculations. (Edit reports are discussed in detail in Section G.)

The MDRI system shutdown occurs about 45 days after the quarter ends. The URAs are generated and tape/data cartridges are created and mailed to all 50 States and the District of Columbia. The States should update their master drug rebate files to reflect information contained on the HCFA tape, verify URA adjustment data with labelers' rebate payments, and incorporate all current quarter URAs into their file for billing purposes. In addition to URA data, the HCFA tape contains an updated labeler contact name and address file. States also should be overlaying their files to reflect this information.

Within 15 days after receiving the URA data tape from HCFA, each State should submit billing invoices to each labeler responsible for any NDCs the State reimbursed a pharmacy for during the past quarter. States also should submit utilization adjustment records (unit changes) for past quarters where units billed are determined to be incorrect.

State invoicing to labelers can be submitted using several mediums. It is the State's option whether to submit invoices in paper form, by diskette, or electronically. HCFA **CANNOT** mandate the reporting media for invoices, however, the collection of the invoice data and its reporting format (data fields/elements) are mandated by approval received from the Office of Management and Budget (OMB). (See State Invoice, Section F.)

For all invoicing, each State must generate a separate record for each NDC billed to the labelers and submit a tape to HCFA containing all billing for the quarter. That is, whatever the State invoices to labelers each quarter, that same information MUST be submitted to HCFA. HCFA uses the utilization data received on the States' tapes for internal studies as well as a mandated annual report to the Congress.

Within 30 days after receipt of the State invoice, labelers are required to pay rebates to States for all invoiced NDCs, except for those which are disputed by the labeler. A dispute relates only to the number of units invoiced per NDC. The dispute can involve the entire number of units per NDC, or any portion thereof. (The Dispute Resolution Process is discussed in Section K of this guide.)

Because labelers are responsible for paying the correct rebate amount, a labeler must recalculate/adjust the RPU reported by the State if current data supports an adjustment. Additionally, **under certain limited circumstances**, labelers may adjust the number of units reported per NDC. These two types of adjustments ARE NOT considered disputes. (See Section F for a detailed discussion of labeler adjustments to invoices.)

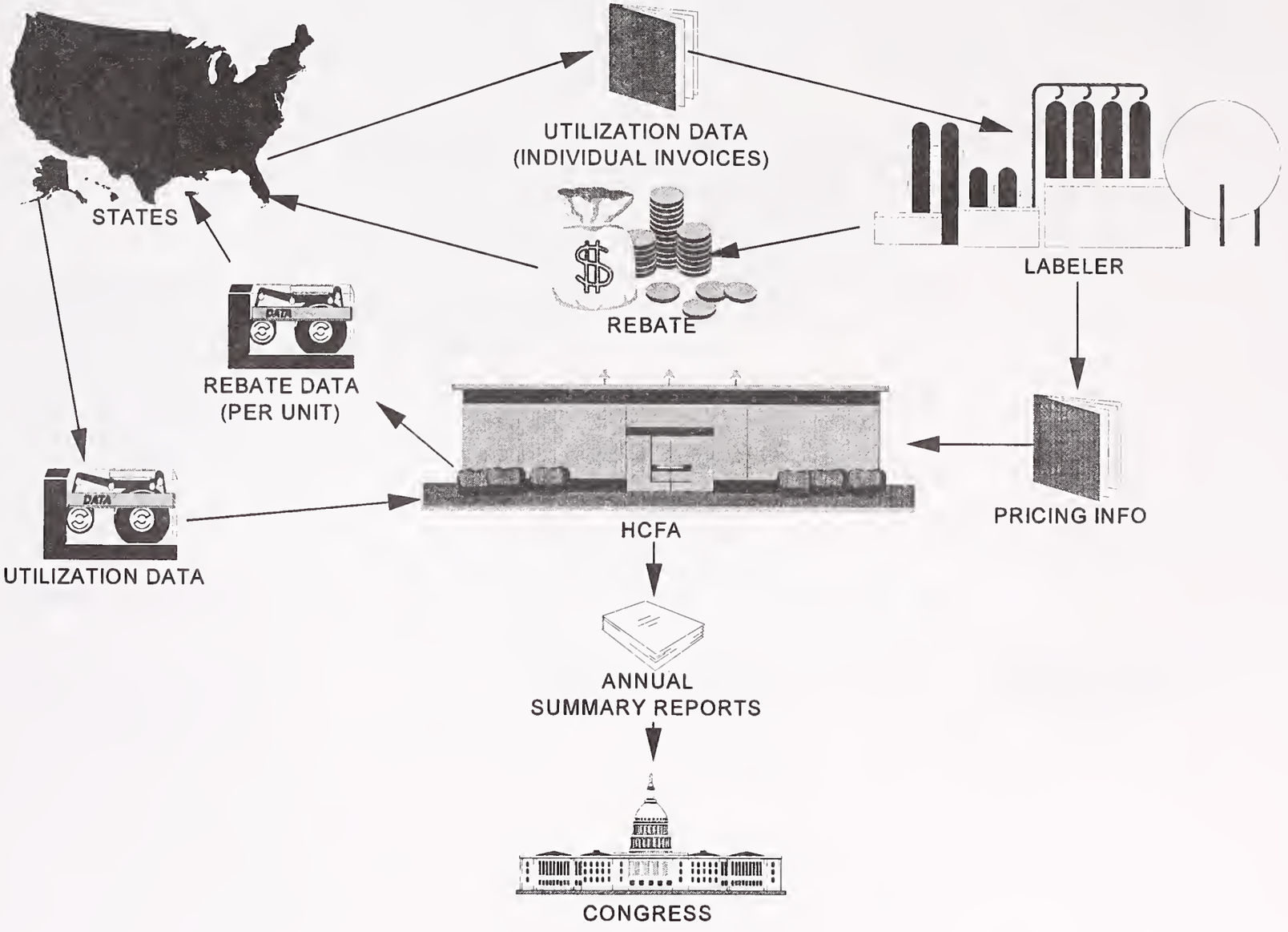
In addition to product data reporting, labelers are required to report administrative data to HCFA. This data consists of contact individuals involved in the program, a list of States with which the labeler has a current rebate agreement, and a data transmission option form. The latter two of these requirements (form HCFA-367b and c) are generally considered a one-time submittal, but can be updated as the need arises. Historically, the labeler contact data is ever-changing and labelers are required to submit these changes on the OMB approved form, HCFA-367a.

States also are required to report administrative data to HCFA consisting of contact individuals for technical, policy, and invoice matters. Form HCFA-368 was developed and approved by OMB for this purpose.

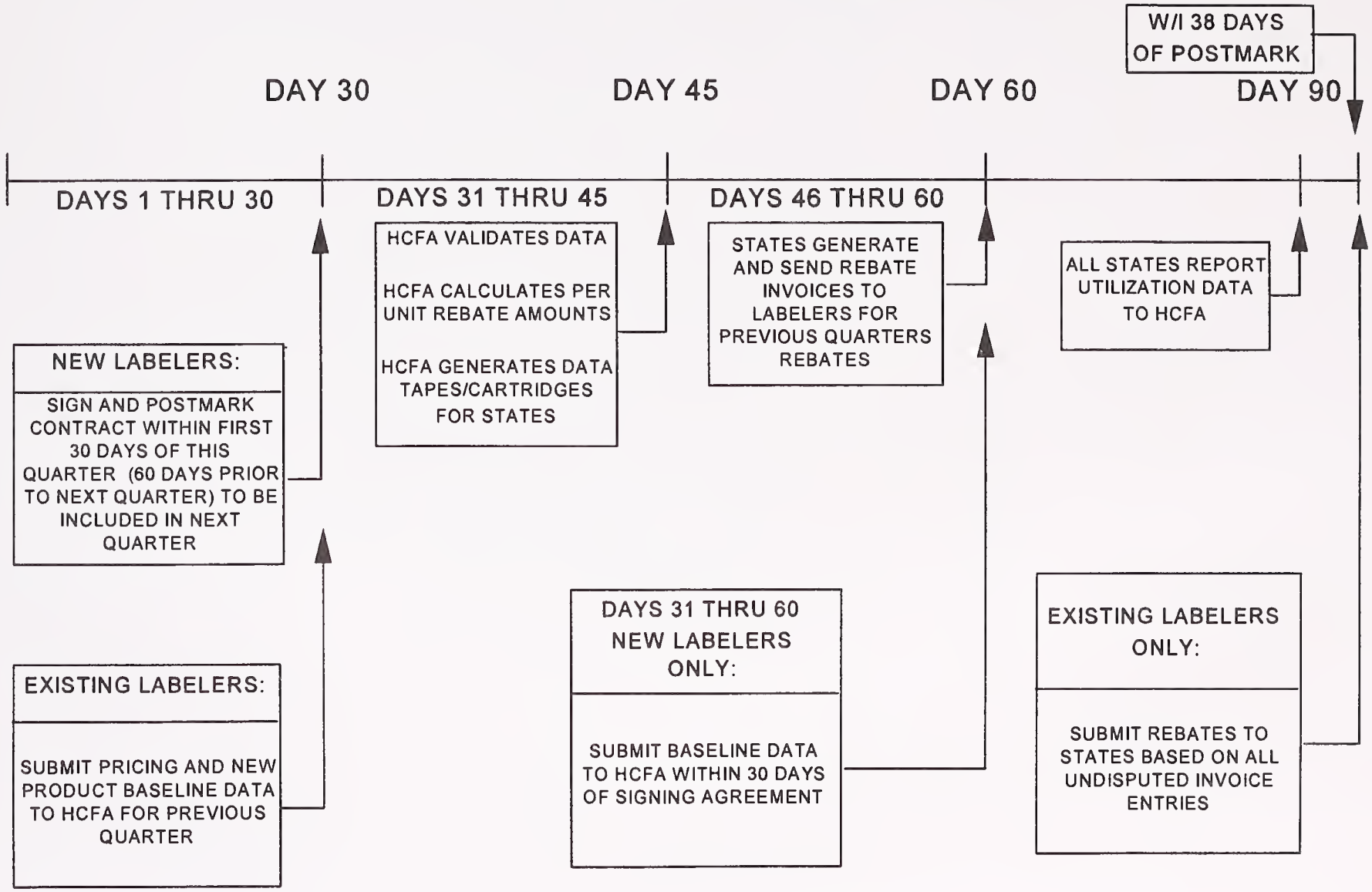
Labelers and States are encouraged to keep HCFA current regarding their list of contacts to assure that the correct individuals are contacted regarding any problems with pricing data, utilization data, receipt of invoices, legal matters, and receipt of HCFA's program releases.

As mentioned above, HCFA uses its quarterly State data tape to provide updates of labelers' contacts to all States. This information helps to promote better communication and assists the States in assuring the invoice is sent to the appropriate labeler contact.

MEDICAID DRUG REBATE PROGRAM



MEDICAID DRUG REBATE PROGRAM
QUARTERLY EVENT TIMELINE



PROGRAM

REQUIREMENTS

PREFACE

In this section, we will be discussing the data elements included on the HCFA URA quarterly tape sent to all States. This preface is an explanation of why it is imperative that States use data fields from the HCFA URA quarterly tape, rather than values from independent software companies that supply data to the States.

Quarter after quarter, HCFA receives phone calls from drug labelers stating that:

- the URA(s) reported by States on the invoice does not match what should have been calculated from the AMP/BP values sent to HCFA;

- the units reported on the invoice do not match a multiple of the labeler's UPPS supplied with their Baseline data; and

- the Unit Type does not match that which they supplied to HCFA.

Information on the HCFA URA tape, such as Unit Type and UPPS are created from values supplied by labelers. These values (e.g., 30 ML rather than 28.7 ML = 1 oz for a tube of ointment, or "GM" instead of "EA" for a powder-filled vial that has multiple package sizes) are used by the labelers when calculating their AMP and BP values. Whatever values are used by a particular labeler, those values are reported to HCFA and are contained on the quarterly URA tape.

Another value contained on the URA tape is the DESI value. This DESI value is used by HCFA in determining whether Federal Financial Participation (FFP) will be paid IN THE FOLLOWING QUARTER for a given product. If a State uses a DESI code from an outside source, it could be paying for a drug for which FFP is not available.

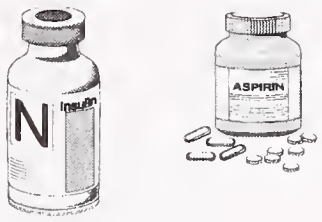
By using values supplied by an outside concern, the States run the risk of using values inconsistent with those of the labelers. The use of such values causes erroneous data in the State's system, delayed processing of invoices by the labelers, possible loss of FFP, and is often a major reason for disputes.

In an attempt to prevent the use of incorrect data values, HCFA sends a copy of its quarterly URA tape, **MINUS URA VALUES**, to Medispan and First Databank, the two major suppliers of drug data to States. These companies are supposed to match the HCFA tape to their own files and, where discrepancies exist, use HCFA values rather than their own. Bottom line: the HCFA data files are considered correct, until proven otherwise.

PRODUCT DATA
AND
REPORTING REQUIREMENTS

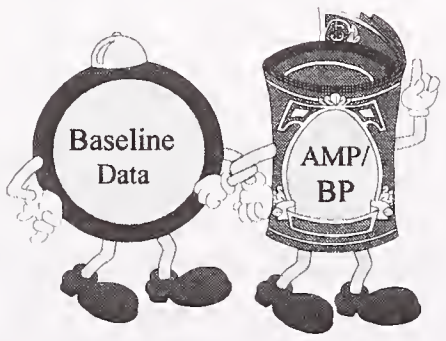
When a labeler requests, and receives, a Medicaid Drug Rebate Agreement from HCFA, several forms/record layouts are included so the labeler has the data field and record layout information needed to submit Baseline and quarterly pricing data. The OMB approved form required for reporting pricing data is form HCFA-367. A copy of this form and its specific data requirements are provided in this Section.

Within 30 days of receiving notification from HCFA about being accepted into the program and what the effective date is, the labeler is required to supply "Baseline" data on <u>ALL</u> its existing NDCs for drug products that can be prescribed and dispensed as outpatient drugs.



FOR EACH QUARTER THEREAFTER, pricing data is due <u>within 30 days</u> after the quarter is concluded.

Along with the quarterly pricing data, labelers must submit Baseline/AMP/BP data for any new products from the day they were made available for sale in that quarter, any prior quarter's AMP/BP corrections, and Baseline changes.



There always seems to be some confusion, especially with new labelers, about what is Baseline data and what is Pricing data and what is the difference between them. Hopefully, the following will make it all clear.

Baseline data is information about a product that HCFA needs in order to know how the rebate should be calculated, what unit the pricing reflects, whether it is a DESI product, and, therefore, if covered, if it is therapeutically equivalent, etc. In other words, Baseline data is a profile of the product. EVERY NDC that can be dispensed and billed as an outpatient drug, including separate baseline records for multiple package sizes, is to be submitted with ALL pertinent Baseline data included. The reporting quarter/year for <u>all</u> Baseline data is to be designated as 31990 regardless of when the product entered the market. Baseline data fields include:

❶ NDC Number
❷ Drug Category
❸ Therapeutic Equivalency Code
❹ DESI Indicator
❺ Date Entered Market
❻ Unit Type
❼ Units Per Package Size
❽ FDA Approval Date
❾ Product Name
❿ Drug Type

<u>Baseline Update Fields</u>

❶ Correction Flag
❷ Termination Date

✎**NOTE:** Baseline AMP is a field that is required for "S" and "I" (Single-Source and Innovator) drugs having a Market Date PRIOR TO 10-01-93 only. All "S" and "I" drugs having a Market Date EQUAL TO OR GREATER THAN 10-01-93 and all "N" drugs do not require Baseline AMP reporting.

BASELINE DATA FIELDS - DEFINED

- **NDC** } The entire reporting system is geared to the product's NDC. This code is broken into three distinct parts:

  - NDC 1 is the 5-digit "labeler" code **assigned to labelers by the FDA.**

  - NDC 2, the second part of the NDC, is the 4-digit number **assigned by labelers** to a given product.

  - NDC 3 is the last 2-digit part that **labelers assign** to the package size(s) of a product.

- **Drug Category** is a 1-digit code designating whether a product is classified as Single-Source (S), Innovator (I), or Non-Innovator Multiple-Source (N).

- **Therapeutic Equivalence Code** is a 2-digit code that begins either with an "A" (therapeutically equivalent to other products), a "B" (NOT therapeutically equivalent to any other drugs), or contains the 2-digit "NR" (not rated) rating. Products are considered equivalent **IF** they contain the same active ingredients, are of the same dosage form, and are identical in strength.

- **DESI** (Drug Efficacy Study Implementation) drugs are those which lack substantial evidence of effectiveness, i.e., less than effective (LTE) and are subject by the FDA to a Notice Of Opportunity for Hearing (NOOH). DESI codes have values of "2" through "6." Drugs listed with DESI code values of "2", "3", or "4" are rebatable. Those listed with DESI code values of "5" or "6" are not rebatable.

- **Date Entered Market and FDA Approval Date** MUST both be included for Baseline data. The FDA Date must be equal to or less (older) than the Market Date. Market Date is the date the product was first offered for sale. FDA Date is the date of FDA Approval. If the product is an over the counter (OTC) that does not need an FDA Date, the Monograph date is used in its place. If the product is a NEW PACKAGE SIZE of an existing product, **DATES MUST** reflect the original product.

- **Unit Type and Units Per Package Size** (UPPS) must be developed together in order to work correctly in the system. There are 7 specific Unit Type values plus "EA" (each) for certain types of products. The Unit Type **MUST BE** designated as the smallest unit for which the product can be dispensed. This is what ALL PRICING is based on. AMP, BP and (where required) Baseline AMP reflect the price of ONE OF WHATEVER IS THE UNIT TYPE. Thus, if the Unit Type is "ML," pricing reflects ONE ML. The UPPS value depends on whether the package can be broken and dispensed in smaller amounts. An example is a product with a Unit Type of "CAP" (capsule). If the product comes in a bottle of 100 CAPs that MUST be dispensed as is, the UPPS equals 100. If, however, the product comes in a bottle of 100 that a pharmacist may open and dispense 10, 20, 50, etc., CAPs at a time, the UPPS is equal to 1. In ALL cases, the prices reflect 1 capsule. This is one of the few conditions where a field (in this case, UPPS) can contain different values for different package sizes of a given product. In most cases, the information is the same across all package sizes. UPPS, however, can equal 1 for one package size and 100 for another. A further detailed discussion of UPPS is provided later in this Section.

- **Product Name** is the name the product is registered under with the FDA. There are up to 63 characters allowed for this field.

- **Drug Type** is a 1-position field that contains a "1" if the product is a prescription and a "2" if it is an OTC.

- **Correction Flag** is "1" if this is a correction record, otherwise, it is left blank. THIS FIELD IS USED ONLY FOR UPDATING EXISTING BASELINE DATA.

- **Termination Date** is determined by the reason the product is being discontinued. If it is being pulled from the shelf immediately, due to a health or safety reason, whether it be by FDA or labeler directive, the Termination Date is the date it is removed. If, however, it is being replaced by an improved version, or discontinued due to low sales, the Termination Date is the shelf life of the last batch sold. THE TERMINATION DATE IS LEFT BLANK UNLESS AND UNTIL ONE OF THE ABOVE CONDITIONS OCCURS.

  In **all** cases, labelers are required to submit prices to HCFA for FOUR QUARTERS BEYOND the termination date. The last calculated AMP, and where applicable, BP, are to be reported each quarter for this time period, with one exception. This exception is when a product has several package sizes and at least one is being terminated. The AMP/BP calculations for the **active** package sizes are to be done normally. These same active calculated AMP/BP values are to be reported for the terminated package size for four quarters beyond the termination date.

Pricing data consists of:

- ✓ the AMP for EACH NDC; and
- ✓ BP for all "S" and "I" NDCs.

This data is due within 30 days after the end of a calendar quarter.

Pricing data fields include:

1. Reporting quarter and year (QYY);
2. NDC;
3. AMP; and
4. BP (for "S" and "I" NDCs).

DATE: ___/___/_____
MM/DD/YYYY

PAPER REPORTING FORMAT
LABELER QUARTERLY PRICING DATA

QUARTERLY REPORT FOR QUARTER ____ CALENDAR YEAR _____

FDA ASSIGNED LABELER CODE _____

PRODUCT CODE	PACKAGE SIZE	DRUG CAT.	THERA. EQ. CODE	DESI IND.	AVERAGE MANUFACTURER PRICE	BEST PRICE	DATE ENTERED MARKET
_____	____	__	____	__	_____.___	_____.___	____/____/____

BASELINE AMP	TERMINATION DATE	CORR. FLAG	UNIT TYPE	UNITS PER PACKAGE SIZE	FDA APPROVAL DATE
_____.___	____/____/____	__	____	_____.___	____/____/____

PRODUCT NAME _____ ___
DRUG TYPE

PRODUCT CODE	PACKAGE SIZE	DRUG CAT.	THERA. EQ. CODE	DESI IND	AVERAGE MANUFACTURER PRICE	BEST PRICE	DATE ENTERED MARKET
_____	____	__	____	__	_____.___	_____.___	____/____/____

BASELINE AMP	TERMINATION DATE	CORR. FLAG	UNIT TYPE	UNITS PER PACKAGE SIZE	FDA APPROVAL DATE
_____.___	____/____/____	__	____	_____.___	____/____/____

PRODUCT NAME _____ ___
DRUG TYPE

MEDICAID DRUG REBATE PROGRAM
QUARTERLY PRICING DATA DEFINITIONS
(FORM HCFA-367)

DATA ELEMENT NAME:	Labeler Code - First segment of National Drug Code that identifies the manufacturer, labeler, relabeler, packager, repackager or distributor of the drug. Numeric values only, 5 digit field, right justified and 0-filled for 4 digit labeler codes.
DATA ELEMENT NAME:	Product Code - Second segment of National Drug Code. Numeric values only, 4 digit field, right justified, 0-filled.
DATA ELEMENT NAME:	Package Size Code - Third segment of National Drug Code. Two digit field, right justified, 0-filled.
DATA ELEMENT NAME:	Period Covered - Calendar quarter and year covered by data submission. Numeric 5 digit field, QYYYY Valid values for Q: 1 = January 1 - March 31 2 = April 1 - June 30 3 = July 1 - September 30 4 = October 1 - December 31 Valid values for YYYY: Four digit calendar year covered. For Baseline data submission, indicate third quarter of 1990 as 31990.

MEDICAID DRUG REBATE PROGRAM
QUARTERLY PRICING DATA DEFINITIONS
(FORM HCFA-367)

DATA ELEMENT NAME:	Product Registration Name - Product name as it appears on FDA registration form. Alpha-numeric values, 63 characters, left justified.
DATA ELEMENT NAME:	Drug Category - Classification of drug for purposes of rebate calculations. Alpha-numeric values, 1 character. Valid values: N = Non-innovator multiple source S = Single source I = Innovator multiple source
DATA ELEMENT NAME:	DESI Drug Indicator - A DESI drug is any drug that lacks substantial evidence of effectiveness (less than effective (LTE)) and is subject by the FDA to a Notice of Opportunity for Hearing (NOOH). This includes drugs which are identical, related or similar (IRS) to DESI drugs. Numeric value, 1 digit. Valid values: 2 = Safe and effective or non-DESI drug 3 = Drug under review (no NOOH issued) 4 = LTE/IRS drug for SOME indications 5 = LTE/IRS drug for ALL indications 6 = LTE/IRS drug withdrawn from market

MEDICAID DRUG REBATE PROGRAM
QUARTERLY PRICING DATA DEFINITIONS
(FORM HCFA-367)

DATA ELEMENT NAME: Therapeutic Equivalence Code - The classification as contained in the FDA publication "Approved Drug Products with Therapeutic Equivalence Evaluations" (the FDA Orange Book) for the last day of the calendar quarter for which the rebate payment is being made. Alpha-numeric values, 2 character field.

Valid values:

AA	BC	BS
AB	BD	BT
AN	BE	BX
AO	BN	NR - Not rated
AP	BP	A1 thru A9 = AB value
AT	BR	

MEDICAID DRUG REBATE PROGRAM
QUARTERLY PRICING DATA DEFINITIONS
(FORM HCFA-367)

DATA ELEMENT NAME: Unit Type - Basic measurement that represents the smallest unit by which the drug is normally measured. The rebate amount will be calculated per unit.
Alpha-numeric values, 3 character field, left justified.
Valid values:

AHF =	refers only to injectable Anti-Hemophilic Factor (AHF) units
CAP =	Capsule
SUP =	Suppository
GM =	Gram
ML =	Milliliter
TAB =	Tablet
TDP =	Transdermal Patch
EA =	EACH (Refers to drugs not identifiable by any other unit type as given in program instructions.)

DATA ELEMENT NAME: Units Per Package Size Code - Total number of units, as defined in the Unit Type field, in the smallest dispensable container or entity for the product defined by the full NDC.
Numeric values, 10 digit field: 7 whole numbers and 3 decimal places.

MEDICAID DRUG REBATE PROGRAM
QUARTERLY PRICING DATA DEFINITIONS
(FORM HCFA-367)

DATA ELEMENT NAME:	AMP (Average Manufacturer's Price) - The AMP per unit per product code only for the period covered, based on sales. If a drug is distributed in 3 package sizes, there will be one "weighted" AMP for the product, which will be the same for all package sizes. Numeric values, 11 digit field: 5 whole numbers and 6 decimal places. Compute to 7 decimal places, and round to 6 decimal places.
DATA ELEMENT NAME:	Baseline AMP - The Average Manufacturer's Price per unit per product code. If a drug is distributed in 3 package sizes, there will be one "weighted" AMP for the product, which will be the same for all package sizes. For ALL "S" and "I" drugs marketed AFTER 09-30-90, REGARDLESS OF FDA APPROVAL DATE, the Baseline AMP is determined by the AMP for the first day of the first full month in which the drug was first marketed. NOTE: Effective for all quarters beginning with 10-01-93, the Baseline AMP for these products is to be reported as "0", and is subsequently determined by the AMP for the first full quarter AFTER the product is marketed. Numeric values, 11 digit field: 5 whole numbers and 6 decimal places. Compute to 7 decimal places and round to 6 decimal places. Zero fill for Non-innovator Multiple Source drugs.

MEDICAID DRUG REBATE PROGRAM
QUARTERLY PRICING DATA DEFINITIONS
(FORM HCFA-367)

DATA ELEMENT NAME:	Best Price - The lowest price available from the labeler to any wholesaler, retailer, nonprofit entity, or governmental entity within the United States (excluding depot prices and single award contract prices of any agency of the Federal Government). Effective 10/01/92, manufacturers must exclude any prices charged to the following entities: the Indian Health Service; the Department of Veterans Affairs; a State home receiving funds under section 1741 of title 38, United States Code; the Department of Defense; the Public Health Service (PHS) or any entity described in section 340B(a)(4) of the PHS Act and as further specified in Federal Register notices; the Federal Supply Schedule; and, a State pharmaceutical assistance program. **The Best Price is the lowest price, regardless of package size, for the same product code.** Numeric values, 11 digit field: 5 whole numbers and 6 decimal places. Compute to 7 decimal places, and round to 6 decimal places. Zero fill for Non-innovator-Multiple Source drugs.

DATA ELEMENT NAME: FDA Approval Date - Date of FDA approval of the NDA, without regard to whether the drug has been sold or transferred to any entity, including a subsidiary or division of the original manufacturer. For OTC drugs, use Monograph date. Numeric values, 8 digit field, (MMDDYYYY).

DATA ELEMENT NAME: Date Drug Entered Market - If marketed prior to 10-01-90, first day of the first month that the drug was marketed for the entire month; otherwise, actual date the product is marketed. Numeric values, 8 digit field, (MMDDYYYY).

DATA ELEMENT NAME: Drug Termination Date - Date drug was withdrawn from market or shelf life of last lot sold if no longer distributed by labeler. Numeric values, 8 digit field, (MMDDYYYY).

DATA ELEMENT NAME: Drug Type Indicator - Indicator to show whether this drug product can be acquired only by prescription or can be acquired OTC.

1 = Rx
2 = OTC

DATA ELEMENT NAME: Correction Record Flag - Indicator that this record corrects and replaces a record already submitted for the initial submission. Numeric value, 1 digit field.

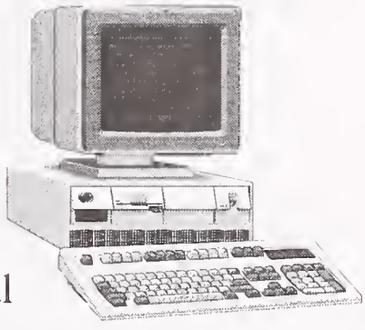
Valid values: 0 = Original record
1 = Correction record

DATA REPORTING

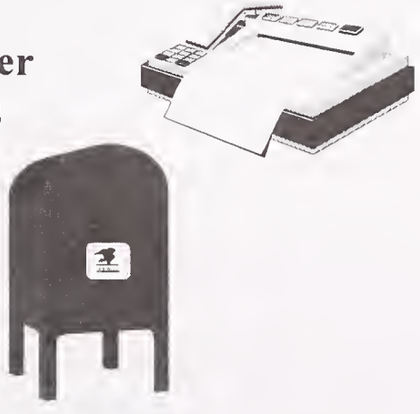
Baseline and Pricing data can be submitted in one of three ways. When the Drug Rebate Agreement is signed, labelers are given three data transmission options to choose from:

1. **Electronic** data submission can be done by setting up a contract with the Ordernet company for an electronic mailbox. HCFA supplies the telephone number, record layouts, and instructions for getting started.

2. A **personal computer** menu-based system is provided by HCFA free of charge for those electing this option. HCFA maintains this system, updates it as required, and includes a run book for instructional purposes.



3. For small companies, **paper** submission is permitted as long as it is sent/faxed on the required form HCFA-367. **This method is reserved for companies having 5 or fewer NDCs.**



Data correction reporting requirements are different for Pricing data and for Baseline data.

➳ For pricing (AMP/BP) corrections the required fields are:

1. NDC
2. Quarter Affected
3. Correct AMP/BP
4. Correction Flag (set to "1")

➳ For Baseline changes/corrections: ALL fields, except AMP/BP, are required.

✎**NOTE**: All fields not changed are to contain current values. Changed fields are to contain corrected field values. Submitting Baseline changes with only the affected field(s) will result in the record being rejected by the edit program.

REPORTING DEADLINES

Pricing data and, when needed, Baseline data is due to HCFA within **30 days after the end of each calendar quarter** as shown below.

QUARTER	DUE DATE
January-March	April 30
April-June	July 30
July-September	October 30
October-December	January 30

If the data is not submitted timely, several things could be affected. First, HCFA maintains an edit program through which ALL data is run. Edit reports are produced for rejected records. HCFA sends these reports to labelers as quickly as possible for correction. If corrected data is returned

quickly enough, it is included in HCFA's quarterly URA calculation which is reflected on the State tapes. If the corrected data or edit corrections are not sent to HCFA on time, the URA for affected NDCs will not be included on the State tapes for that quarter. (The URA will, however, be included in the subsequent quarterly tape to States.)

Second, THE EXCLUSION OF UNTIMELY DATA MEANS THAT LABELERS ARE RESPONSIBLE FOR CALCULATING THEIR OWN UNIT REBATE AMOUNTS AND REMITTING THE APPROPRIATE REBATE TO THE STATE.

Third, if a labeler fails to submit data for two consecutive quarters, HCFA sends a letter stating that, unless the missing data is submitted within a certain time, the labeler's rebate agreement WILL BE TERMINATED. ☹

No Price Changes = No Pricing Changes, OR DOES IT?

One question often raised concerns the reporting of pricing data when labeler prices do not change from quarter to quarter. In this case, the question is: **Are labelers still required to report (this same) pricing data quarter after quarter? The answer: Yes!**

Other than the statutory requirement, the first and most important reason for continuous reporting relates to the AMP calculation. Because of this sales/units calculation, it IS possible for pricing to change, even though labeler prices do not change. For example, this can occur when a large volume of discounts is applied in a given quarter (usually the last), but not in other quarters. Therefore, two consecutive quarters could have the same exact sales; however, the NET dollars are different and the NET units are the same. In this situation, the current AMP will differ from the last quarter's, even though the labeler's price remains the same.

Second, if labelers do not report pricing data each quarter, HCFA has no way to determine if the lack of reporting is due to no price changes (which must be reported anyway), or to labelers not fulfilling their contractual obligations under the rebate agreement.

CALCULATING AMP

There's no magic to this process and you certainly don't need this ole wise one to help you. Just read the next few paragraphs and you'll be an expert at it.

Basically, AMP is calculated as NET quarterly sales divided by the number of units sold.

Net sales is derived after all required adjustments are made (discounts, rebate for breakage, etc.). Total units sold MUST BE ADJUSTED for returns, charge backs, etc. If there are multiple package sizes of the same product (NDC 1 and NDC 2 are the same; but, NDC 3 is different), total units sold (for all package sizes) is divided into total net sales dollars (for all package sizes) giving a WEIGHTED AMP for the product. This weighted AMP is to be used for ALL records of the same product.

All pricing is calculated by the UNIT TYPE supplied with the Baseline data. Therefore, if a given product is listed with a Unit Type of ML, ALL pricing must be shown on a per ML basis. If the product is sold in a 30 ML tube, the pricing must be shown as the price of **ONE** ML, NOT 30. (See other portions of this Section for discussions on Unit Type and UPPS.)

BEST PRICE

Best Price (BP) is similar to the AMP calculation in that it is the same for all package sizes of a given product; **however, it is NOT weighted**. Instead, BP is the LOWEST price the product is sold for, regardless of package size.

✎**NOTE**: Because of discounts, returns, seasonal sales, etc., there can be occasions when AMP could calculate as lower than BP. **In this case, always report BP as equal to the calculated AMP.**

Bundled Sales

As stated in the Drug Rebate Agreement "Bundled Sales" refers to the packaging of drugs of different types where the condition of a rebate or discount is that more than one drug type is purchased, or where the resulting discount or rebate is greater than that which would have been received had the drug products been purchased separately. The key to identifying a bundled sale is that the sale is contingent on the purchase of another product(s).

For example, buy one bottle of pills and get the second bottle at 50% off, buy one tablet and get a bottle of cream free. Note that in the second example with the free cream, the cream is not considered "free goods" as defined in the Drug Rebate Agreement because the item is not given free, it is contingent on the purchase of the tablet. The only "free goods" are those given as free samples (no sales attached) and which are not contingent on the purchase of another product(s).

Bundled Sales will affect the AMP and BP calculations. The value of the discounted or free product should be proportionately distributed among the other products in the bundle. To accomplish this, follow the two steps listed below.

❶ Determine the value of the free or discounted product by determining the AMP of the product in the same quarter if sold alone (prior to bundling). The value of this product will be considered a discount which should be applied to the other products within the bundle.

❷ Refigure the AMP/BP of the products within the bundled sale by applying the value of the discounted/free good among the other products.

The following page offers an example of an AMP and BP calculation under a bundled sales situation.

CALCULATION OF AMP FOR BUNDLED SALES

❶ Calculate AMP "Unbundled"

1st NDC: net sales = 100 TAB for $100 = $1.00 AMP per TAB
2nd NDC: net sales = 100 ML for $200 = $2.00 AMP per ML
3rd NDC: net sales = 100 GM for $10 = $0.10 AMP per GM

THE DEAL

Buy the first 2 products (100 TAB & 100 ML), get the 3rd product (100 GM) free. The "free" product is contingent upon buying the first 2 products.

Under the "unbundled" calculation, the total selling price for these products would be $310 ($100 + $200 + $10). By giving the 3rd product for free if the first two are purchased, the sales amount decreases to $300 ($310 - $10). Divide the $300 by the "unbundled sales amount ($310) and subtract that percentage (97%) from 100% to derive at a resulting discount of 3%. Therefore, a discount of 3% should be applied to each product selling price in order to calculate the revised AMP.

❷ The "Revised" AMP

1st NDC: $100 x 3% = $3.00 discount
2nd NDC: $200 x 3% = $6.00 discount
3rd NDC: $10 x 3% = $.30 discount

1st NDC: $100 - $3.00 = $97.00 for 100 TAB = .97 AMP*
2nd NDC: $200 - $6.00 = $194.00 for 100 ML = 1.94 AMP*
3rd NDC: $10 - $.30 = $9.70 for 100 GM = .097 AMP*

*These revised AMP figures would be applied to determine BP.

Units Per Package Size

UNITS PER PACKAGE SIZE (UPPS)
HOW, WHEN AND WHY

The UPPS field was designed so that utilization totals from States to labelers would be as accurate as possible when "unbreakable" packages are reported. For every NDC, the UPPS contains a value of either "1" if the package ***can be*** broken by the pharmacist to dispense fewer units than the package contains, or, the ACTUAL UNIT VALUE of the package if it ***cannot*** be broken.

By and large, over-the-counter products fall into the ***unbreakable*** package category, with very few exceptions.

The package category for prescription drugs varies, however, based on the product and size of package.

Blister packs, birth control pills, inhalers, and tubes of ointments are examples of prescription drugs that are (generally) ***unbreakable*** packages.

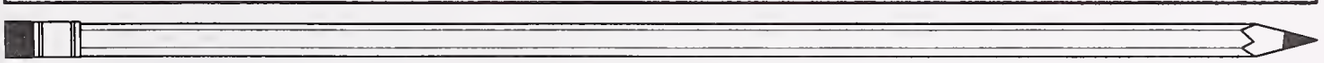
Tablets, capsules, and large bottles of liquid medication are examples of prescription drugs that are, in most cases, dispensed in amounts smaller than what they were originally packaged in (***breakables***).

The reason why the UPPS field (supplied to HCFA by the labeler) MUST BE USED, rather than the field supplied by an outside vendor used by the State for their drug program, is as follows. There is no absolute, set rule about converting milliliters and grams to ounces. Some labelers use the exact equivalence, some use the "accepted" rounded value of 30. HCFA does not require labelers to use either one. What we do require, however, is that a labeler's use of the equivalent remain consistent. If labelers use 30 for the ML to OZ conversion, they must assure that this specific conversion is used 100% of the time. ALL pricing calculations for a product are based on what value a labeler uses.

IMPORTANT !!

It is imperative that States use the UPPS field from the quarterly URA tape supplied by HCFA when calculating their total utilization to be reported to a labeler. The UPPS is to be multiplied by the total number of prescriptions for unbreakable packages, giving States the total utilization for that NDC. If an UPPS field from an outside vendor is used, it may contain a value different from the one reported by the labeler to HCFA. This will cause an invoice to contain invalid units and, in many cases, results in disputes. Disputes caused by the State using the wrong UPPS will ALWAYS be resolved in favor of the labeler.

STATE INVOICE



STATE INVOICE

UTILIZATION DATA REPORTING REQUIREMENTS

States are required by statute to report quarterly drug utilization data to drug labelers participating in the drug rebate program **not later than 60 days** after the end of each rebate period. States also are required to transmit a copy of this quarterly report of utilization data to HCFA.

The law requires that the format for this data submittal be established by the Secretary. The establishment of the reporting format has been delegated from the Secretary to HCFA. In 1991, HCFA, in conjunction with State Medicaid agency representatives, developed the State Invoice (form HCFA-R-144) as the reporting format for utilization data sent to labelers. Approval of the invoice format was obtained from the OMB. OMB approval of the State Invoice mandates its use, i.e., once OMB approves a request for data collection, affected respondents are required to report all data elements, and in the established format. This Section contains form HCFA-R-144, along with the electronic format and the definition of each data element required.

For each covered outpatient drug dispensed **AND** FOR WHICH PAYMENT WAS MADE BY THE STATE, the invoice specifically requires the reporting of the following items for **EACH** NDC number listed by the State.

1. State Code
2. Period Covered
3. Labeler Code
4. Product Code
5. Package Size Code
6. Product FDA Registration Name
7. Rebate Amount Per Unit
8. Total Units Reimbursed
9. Total Rebate Amount Claimed
10. Number of Prescriptions
11. Total Amount Reimbursed by the State
12. Correction Record Flag

Please remember that the utilization data reported on the invoice MUST be based on the date of payment and NOT on the date of service.

State invoices due 60 days after the end of each rebate period should reflect **only those NDCs for the current quarter**. (Invoices reflecting unit adjustments for prior quarters are discussed later in this section.)

Invoices must reflect only those NDCs paid for, in whole or in part, under the Medicaid program.

Invoices MUST NOT REFLECT any NDCs paid for under:

1. **A State-funded only General Assistance program;**
2. **Other State-funded only programs; or**
3. **Other Federal drug rebate programs.**

Invoices containing NDCs other than those required under the Medicaid Drug Rebate Program cause delayed processing by the labelers.

♣ **CLARIFIER**: Portions of this section contain references to URA and RPU. These terms are synonymous in the drug rebate program. URA is mostly used by HCFA when referring to the field on the HCFA State tape containing the unit rebate amount. RPU is used mainly by States and labelers when referring to the field on the Invoice, ROSI, and PQAS containing the rebate per unit. ♣

INVOICING WHEN THE URA IS REPORTED AS ZERO

There are several reasons why URAs are reported as zero on the HCFA State tape, all of which are related to the various pricing data edit reports conducted by HCFA. These reports are fully detailed in Section G of this guide.

WHENEVER ANY OF THESE EDIT REPORTS GENERATE A ZERO URA ON THE HCFA TAPE, STATES **MUST INCLUDE** UTILIZATION DATA ON THE INVOICE FOR THE AFFECTED NDCS, AND REPORT THE RPU AS ZERO.

Generally, most NDCs rejected by the drug rebate edit program contain valid errors. For these true pricing errors causing an RPU of zero on the State invoice, labelers are responsible for calculating the correct RPU, remitting the rebate amount due, and reporting the correct AMP/BP to HCFA prior to, or with, their next quarter's data submission.

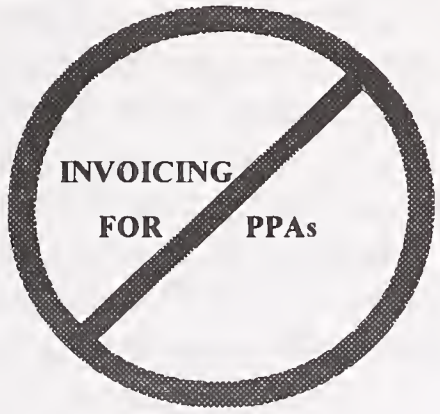
To provide States verification of any labeler calculated RPUs, HCFA's subsequent quarterly tape to the States contains PPAs which reflect old and new URAs for prior quarters based on labelers' submission of corrected pricing data.

TOLERANCE THRESHOLDS

States may apply a $50 tolerance threshold per labeler to its current quarter invoice. Additionally, this $50 tolerance threshold may be applied to invoices prepared for utilization changes for any quarter.

The application of the tolerance for either the current quarter invoice or invoices reporting utilization changes is optional. States may choose to invoice labelers for amounts at or below the tolerance level. When applying the tolerance, States should make the labeler aware of its decision to do so and report the quarter, number of units, and NDC(s) affected to the labeler.

If the tolerance is applied, States must maintain documentation which clearly identifies the labeler code, the NDC number, the applicable quarter, and the amount to which the tolerance is applied. Additionally, States which apply the tolerance level **will not be at risk** for loss of Federal financial participation for amounts at or below the tolerance. (The tolerance threshold for interest is discussed in Section I of this guide.)



The practice of States invoicing for PPAs is no longer permitted. HCFA's August, 1995 decision to shift the PPA responsibility from the States to the labelers is in keeping with the intent of the Federal statute which requires labelers to remit rebate payments to States using accurate pricing data.

To assist States in maintaining their internal accounting systems and to enable labelers to continue to see what States view as PPAs, HCFA suggests that States may opt to attach a PPA listing to their current quarter invoice for informational purposes only. Additionally, the dollar amounts associated with this listing **SHOULD NOT** be a part of the dollars claimed on the current quarter invoice.

✎**NOTE:** Labelers are not obligated to respond to any PPAs incorporated into the State's invoices.

Section J of this guide fully explains the current PPA process and the PPA verification method for both the States and labelers.

SENDING UTILIZATION DATA

TO LABELERS

Although there is a mandated format for the State invoice itself, there is no requirement for the reporting media when States submit their invoices to labelers. States have the option of transmitting invoices to labelers using electronic media, diskette, or paper.

This lack of reporting media requirement has, with good reason, been an issue for discussion since the beginning of the program. Unfortunately, HCFA is unable to mandate the type of media States use to report utilization data to labelers because of the volume and composition of labelers. There are approximately 500 labelers participating in the program at any given time, all with various types and makes of data systems ranging from main frame data bases to personal computer data bases to manual data systems.

Additionally, State agencies maintain various types of data systems, many of which are not compatible with systems currently operated by labelers representing the largest volumes of NDCs. The lack of compatibility with the majority of the systems currently in use make it impossible to mandate any one particular media. Even a "general" mandate of electronic media would force States to purchase and maintain multiple systems to assure compatibility with all labelers. This would create an extreme undo hardship on States which HCFA could not support. HCFA does, however, encourage States to review their system capabilities and report to labelers via electronic media whenever possible.

States should send their invoices to the drug labeler's invoice contact. The HCFA quarterly URA tape to States includes a data set containing an updated list of labeler contacts. This labeler contact file is the second data set on the quarterly tape. Each quarter State systems should assure that the correct contact/address is accessed and used for submittal of the invoice. To maintain and assure the most accurate contact listing, labelers are instructed to advise HCFA in a timely manner of any contact changes.

SENDING UTILIZATION DATA (Cont'd.)

TO HCFA

States are required to report their utilization data to HCFA using magnetic media. States must send either a 6250 BPI IBM Standard Label tape, or a 3480 Cartridge. The characteristics of this media are:

- File Name: .REBATE.Uqyyyy.xx
  where q = quarter
  yyyy = year
  xx = State postal abbreviation

- Record Profile: 80 characters, fixed block, 9,040 characters per block, i.e., 113 records per block.

Send the tape or cartridge to:

Health Care Financing Administration
Office of Information Systems
Attention: Tape Library
7500 Security Boulevard
Baltimore, Maryland 21244

✎ **NOTE:** When HCFA completes its processing of State utilization data tapes, the tapes/cartridges are not returned to the States. Likewise, States are not required to return quarterly tapes/cartridges to HCFA.

States are required to send a tape confirmation letter indicating the file name, volume serial number, and the date the tape was sent to HCFA. (A copy of the confirmation letter should be enclosed with the tape.)

Send the confirmation letter to:

Health Care Financing Administration
Center for Medicaid and State Operations
Mail Stop S3-18-13
7500 Security Boulevard
Baltimore, Maryland 21244

✎ **NOTE: ONLY ONE (1) UTILIZATION DATA TAPE PER QUARTER IS TO BE SUBMITTED TO HCFA.**

SENDING UTILIZATION DATA TO HCFA (Cont'd.)

Information from State utilization tapes is used to prepare HCFA's annual drug rebate Report to the Congress. Therefore, timely submission of these tapes is important and appreciated. It is also imperative that State utilization tapes are submitted timely because the timeliness of these tapes and the notice to HCFA of their submission are a heavily weighted factor (#27) in HCFA's State System Performance Review (SPR) Program. The SPR program provides for States to receive points in this area only if States submit the utilization tapes/notice of mailing within the specified time frame.

In an effort to eliminate many of the errors which hinder HCFA's processing of States' quarterly tapes/cartridges, a checklist was developed for State use. States should make every effort to comply with the checklist. If the standards outlined on the checklist are not met, the HCFA tape librarians will not be able to determine that the tapes are utilization tapes. All unrecognizable tapes/data cartridges are erased by HCFA tape library personnel and made available for re-use internally.

A copy of the checklist is provided on the following page.

MEDICAID DRUG REBATE PROGRAM

STATE UTILIZATION TAPE SUBMISSION PROCEDURES

The HCFA tape library receives a large quantity of tapes from many outside sources. To ensure that your tape is received and processed correctly, please follow the checklist below.

____ Is the correct naming convention used for the data set on the tape? i.e.:

.REBATE.Uqyyyy.xx

where q = quarter
yyyy = year
xx = State postal abbreviation

DO NOT USE FOREIGN.CART.DRqyy.xx or FOREIGN.TAPE.DRqyy.xx

____ Is there an external label on the tape indicating that it is a drug rebate tape? (A label with a data set name containing "DRUG.REBATE.Uqyyyy.xx" is necessary.)

____ Did you generate a confirmation letter indicating the file name, volume serial number, and the date the tape was sent? This letter is to be sent to the following address:

Health Care Financing Administration
Center for Medicaid and State Operations
Mail Stop S3-18-13
7500 Security Boulevard
Baltimore, Maryland 21244

____ Did you enclose a copy of the confirmation letter with the tape and is it being sent to the correct address? The tape is to be sent to the following address:

Health Care Financing Administration
Office of Information Systems
Attention: Tape Library
7500 Security Boulevard
Baltimore, Maryland 21244

____ If you re-used a HCFA tape, YOU MUST REMOVE OR OBLITERATE ALL OF HCFA'S EXTERNAL LABELS AND PLACE A NEW LABEL ON THE TAPE/DATA CARTRIDGE; otherwise, the tape/data cartridge possibly could be returned to blank stock and your data may not get processed.

REPORTING UTILIZATION CHANGES

TO LABELERS

States must submit utilization changes to labelers, using the State Invoice, for individual NDCs when there are changes to:

- the total units reimbursed.

States are strongly encouraged to submit utilization related changes to labelers affecting:

- the number of prescriptions; or
- the total reimbursement amount.

These changes should be reported along with the current quarter utilization data, **BUT NOT** on the same invoice pages as current quarter data. UTILIZATION CHANGES MUST BE REPORTED TO LABELERS USING A SEPARATE INVOICE PAGE FOR **EACH** QUARTER IN WHICH CHANGES OCCURRED. Invoice pages received by labelers containing multiple quarters result in delayed processing of invoices.

Another cause of delayed invoice processing is confusion over which method of reporting utilization changes is used by the State. States must notify labelers of the method used for reporting utilization changes, i.e., a complete overlay of previously reported data, or a +/- to previously reported data. Whichever method is chosen, consistency from quarter to quarter is the primary factor. This notification of the State's method of reporting utilization changes need only be a one-time notice to labelers, unless the reporting method is revised. States may use the short form developed by HCFA for this purpose. A copy of this form is provided on the following page.

Medicaid Drug Rebate Program

State Notification to Labelers of Method Used for Reporting Utilization Changes

TO (Labeler):

FROM (State):

DATE:

Changes to utilization data are reported to you as:

☐ An overlay (replacement) of previously reported units.

☐ A plus or minus to the units previously reported.

TO HCFA

States must submit all utilization changes, i.e., changes to the total units reimbursed, the number of prescriptions, or the total reimbursement amount. These utilization changes must be included on the same quarterly utilization data tape containing the current quarter utilization.

Only one tape per quarter is permitted.

HCFA treats these State correction records as a **replacement** for a record submitted in a prior quarter. Therefore, any correction record received by HCFA completely overlays previously reported data.

For each correction record sent to HCFA, the State must ensure that:

1. The correction flag = "1"; and
2. QYYYY = the pertinent calendar quarter and 4-digit year to which the correction belongs. (This will never be the current calendar quarter/year).

DATE: ___/___/____
MM DD YYYY

STATE OF _____
_____ (Medicaid Agency)

Source: State Agencies
Target: Manufacturers

MEDICAID DRUG REBATE INVOICE

Manufacturer: _____
Address: _____
_____
City: _____ State: ___ Zip: _____

STATE CODE: ____ INVOICE NO.: _____
PERIOD COVERED: _____(QYYYY)

NDC Number	Drug Name	Rebate Amount Per Unit	Total Units Reimbursed	Total Rebate Amt. Claimed	No. of Scripts	Total Reimb. Amount	Corr Flag

MEDICAID DRUG REBATE PROGRAM
ELECTRONIC FORMAT
STATE INVOICE
(FORM HCFA-R-144)

Source: State Agencies
Target: HCFA and Manufacturers

Field	Size	Position	Remarks
Record ID	4	1 - 4	Constant of "01**"
State Code	2	5 - 6	P.O. Abbreviation
Labeler Code	5	7 - 11	NDC#1
Product Code	4	12 - 15	NDC#2
Package Size Code	2	16 - 17	NDC#3
Period Covered	5	18 - 22	QYYYY
Product FDA Registration Name	10	23 - 32	
Rebate Amount Per Unit	11	33 - 43	99999V999999
Total Units Reimbursed	12	44 - 55	999999999V999
Total Rebate Amount Claimed	9	56 - 64	9999999V99
Number of Prescriptions	6	65 - 70	999999
Total Reimbursement Amount	10	71 - 80	99999999V99
Correction Flag	1	81 - 81	See Data Element Definitions

MEDICAID DRUG REBATE PROGRAM
STATE INVOICE
(FORM HCFA-R-144)
DATA DEFINITIONS

DATA ELEMENT NAME:	State Code - Two-character post office abbreviation for State with individual agreement with labeler. Alphanumeric, 2 digits.
DATA ELEMENT NAME:	Labeler Code - First segment of National Drug Code that identifies the manufacturer, labeler, relabeler, packager, repackager, or distributor of the drug. Numeric values only, 5 digit field, right justified, and 0-filled for 4 digit labeler codes.
DATA ELEMENT NAME:	Product Code - Second segment of National Drug Code. Numeric values only, 4 digit field, right justified, 0-filled.
DATA ELEMENT NAME:	Package Size Code - Third segment of National Drug Code. Two-digit field, right justified, 0-filled.
DATA ELEMENT NAME:	Period Covered - Calendar quarter and year covered by data submission. Numeric, 5 digit field, QYYYY. Valid Values for Q: 1 = January 1 - March 31 2 = April 1 - June 30 3 = July 1 - September 30 4 = October 1 - December 31 Valid values for YYYY: All four digits of calendar year covered.

MEDICAID DRUG REBATE PROGRAM
STATE INVOICE
(FORM HCFA-R-144)
DATA DEFINITIONS

DATA ELEMENT NAME:	Product FDA Registration Name (abbreviated) - First 10 characters of product name as it appears on FDA registration form. Alpha-numeric values, 10 digits.
DATA ELEMENT NAME:	Rebate Amount Per Unit - The HCFA calculated amount per unit type to be claimed as a rebate by the State. Numeric values, 11 digits: 5 whole numbers and 6 decimals. Calculate to seven decimals and round to six.
DATA ELEMENT NAME:	Total Units Reimbursed - The total number of unit types of the drug reimbursed by the State during the period covered. Multiply by the per unit rebate amount reported to the State by HCFA to get the total rebate amount for this drug for the quarter. Numeric values, 12 digits: 9 whole numbers and 3 decimals.
DATA ELEMENT NAME:	Total Rebate Amount Claimed - The total rebate amount the State agency claims it is owed by the labeler for the quarter covered. It is calculated by multiplying the total units reimbursed by the rebate amount per unit. Numeric values, 9 digits: 7 whole numbers and 2 decimal places.

MEDICAID DRUG REBATE PROGRAM
STATE INVOICE
(FORM HCFA-R-144)
DATA DEFINITIONS

DATA ELEMENT NAME:	Number of Prescriptions - The number of prescriptions reimbursed for the drug during the quarter. Numeric values, 6 digits, whole numbers only.
DATA ELEMENT NAME:	Total Amount Reimbursed by the State - The total amount the State reimbursed to pharmacists for the drug for the quarter covered. Numeric values, 10 digits: 8 whole numbers and 2 decimals.
DATA ELEMENT NAME:	Correction Record Flag - Indicates that this record is a correction. Numeric values, 1 digit. Valid Values: 0 = original record 1 = correction record

RECONCILIATION OF STATE INVOICE

(ROSI)

RECONCILIATION OF STATE INVOICE
(R O S I)

Within 30 days of receipt of the State's invoice for **current quarter** utilization, labelers are required to remit rebate payments, along with the Reconciliation of State Invoice (form HCFA-304), better known as the ROSI. The ROSI is to be used only to respond to the State's invoice for current quarter utilization. Please ✎**NOTE** that the ROSI form replaces the RAR form previously proposed for this purpose. (Another form, the Prior Quarter Adjustment Statement, was developed and is required for response to items outside the current quarter. That form is discussed later in this Section of the guide.)

The ROSI form (condensed), including complete instructions (data element definitions, adjustment/dispute code listing, and electronic format), and a sample ROSI (condensed) showing examples of how to complete the form are provided in this Section.

REQUIRED USE OF THE ROSI

The Office of Management and Budget has approved HCFA's request for the collection of the data on the ROSI as well as the form itself. Therefore, **labelers are required** to complete and submit the ROSI with each quarterly rebate payment to the State.

The ROSI is required:

① **If** the labeler is NOT paying, in full, the rebate amount due for the current quarter utilization, i.e., the labeler is disputing any units invoiced; or

② **If** the State invoice contains zeros (0s) in the RPU field because no dollar figure has been made available via the HCFA tape (due to the labeler's lack of data submittal), **AND** the labeler is remitting, in full, the rebate amount due for the current quarter utilization.

No additional information may be included on the ROSI and no data element should be omitted unless otherwise instructed by the data definitions.

The requirement for the completion and submittal of the ROSI has three exceptions.

❶ **If** the State invoice contains zeros (0s) in the rebate per unit (RPU) field where a dollar figure has been made available via the HCFA tape, **AND** the labeler is remitting, in full, the rebate amount due for the current quarter utilization. Labelers MUST, however, return a copy of the State's invoice with the rebate payment in full, and may optionally pen/ink the RPU field on the invoice copy.

❷ **If** the State invoice contains zeros (0s) in the RPU field due to HCFA data edits, **AND** the labeler is remitting, in full, the rebate amount due for the current quarter utilization. Labelers MUST, however, make pen/ink changes to the RPU on a copy of the State's invoice and return it with the full remittance.

❸ **If** there are no zero (0) RPU amounts reported on the State's invoice, **AND** the labeler is remitting, in full, the rebate amount due for the current quarter utilization. Labelers MUST, however, return a copy of the State's invoice with the rebate payment in full.

✎**NOTE**: Labelers may optionally chose to complete and submit the ROSI each quarter regardless of the exceptions listed above.

TRANSMITTING THE ROSI

The ROSI may be completed and submitted to the State in one of two media, paper or electronic, depending on the needs and capabilities of the labeler. An electronic transmission format is provided with the ROSI instructions. Labelers **MUST submit the ROSI data to the State in the required format regardless of the transmission media selected.**

♣ **CLARIFIER**: Portions of this section contain references to URA and RPU. These terms are synonymous in the drug rebate program. URA is mostly used by HCFA when referring to the field on the HCFA State tape containing the unit rebate amount. RPU is used mainly by States and labelers when referring to the field on the Invoice, ROSI, and PQAS containing the rebate per unit. ♣

REVIEWING THE STATE INVOICE

Before remitting a rebate payment, labelers should review the invoice to determine whether they are in agreement with information reported by the State. For example: Is the RPU correct? Are there any unit discrepancies, or inconsistencies, e.g., GM v. ML, units v. scripts? Does the invoice contain NDCs which are discontinued/terminated or invalid/miscoded?

When completing the ROSI, labelers may adjust items reported on the State invoice such as the RPU and the number of units (only under limited circumstances), and, as a result of adjustments to these items, the rebate amount claimed on the invoice. Whenever an adjustment is reported on the ROSI to either the RPU or the number of units, labelers **MUST** report a corresponding adjustment code in the space provided. A list of adjustment/dispute codes is attached to the ROSI instructions in this Section.

Labelers **are not permitted**, except under limited circumstances, to change the number of units invoiced by the State. The circumstances under which labelers may adjust the units invoiced are listed below and fully outlined in appendix B to the ROSI instructions. These circumstances lend themselves to an immediate resolution of specific invoice discrepancies, as discussed later in this Section.

The limited circumstances under which a labeler may adjust the number of units reported by the State are:

① Mutual agreement between State/labeler through correspondence/telephone contact.

② Mutual understanding between State/labeler regarding routine adjustments.

③ Obvious non-routine errors; no response by State to labeler's correspondence/telephone call attempting agreement of an adjusted number.

Under no circumstances, other than those listed above, can a labeler adjust the units invoiced by the State. The above circumstances were developed by the Remittance Advice Report Workgroup to assist in reducing the number of units disputed.

Once units are adjusted under the above circumstances, if needed, the remaining units are, of course, subject to dispute. Any adjustments to units after they are officially disputed are made **only by the State** and must be determined using the documentation presented by the labeler and the State under the Dispute Resolution Process. (This process is discussed fully in Section K of this guide.)

IMMEDIATE RESOLUTION OF INVOICE DISCREPANCIES

Items on the invoice for which labelers disagree, may or may not lend themselves to immediate resolution. Immediate resolution can occur when labelers contact the State to discuss what appear to be obvious data errors or entries which the State would most likely agree need correcting. For example:

1. An RPU that does not reflect any data reported to HCFA.
2. Decimal rounding.
3. Unit of measure conversion.

The best way to immediately resolve obvious errors is for labelers to speak directly with the State regarding specific data on the invoice. If time permits, immediate resolution can be accomplished via written correspondence.

In some cases, labelers have an understanding with States which permits the correction of obvious errors, such as decimal rounding, without discussion.

Immediate resolution also can occur even when the disagreement involves the number of units. For example, an inadvertent error resulting in an invoice entry of 100,000 units instead of 10,000 units can be immediately resolved with one phone call ☎. This type of resolution reduces and oftentimes eliminates the necessity to dispute the number of units invoiced.

REBATE PER UNIT

Because labelers are responsible for remitting **accurate** rebate payments, **the current RPU must be applied to the units being paid**. Therefore, if the RPU reported by the State is incorrect, or zero, labelers **MUST** use, and report back to the State on the ROSI, the correct RPU. Whenever the RPU is corrected on the ROSI, the appropriate adjustment code **must be** annotated in the space provided.

✎**NOTE**: Labelers are required to report to HCFA any pricing data changes in a timely manner. By meeting this obligation, labelers assist HCFA in reporting the most accurate URA to States, which in turn decreases the number of incorrect, or zero RPUs on the State's invoice. (Pricing data submission requirements are fully discussed at the beginning of this Section.)

The RPU may or may not be considered an immediate resolution item. However, if other items are discussed with the State for immediate resolution, labelers should inform the State that they are making an RPU adjustment.

ADJUSTMENT/DISPUTE CODES

The ROSI instructions contain a listing of various adjustment/dispute codes labelers must enter, as appropriate, for any adjustments and/or disputes reported to the State. These codes are generic enough in nature to accommodate any adjustment or dispute which may occur. Although codes A-I are used generally as adjustment codes, and codes N-W are used generally for disputes, some codes may be appropriate for either situation. Labelers should not use any codes other than those provided on the listing.

The format of the ROSI, paper or electronic, is designed to accommodate a maximum of three (3) codes each for adjustments and disputes per NDC. Generally, labelers should attach supporting documentation, as needed, for any code selected to further explain the reason for the adjustment/dispute. However, labelers MUST supply documentation for any code where specifically required on the listing.

MEDICAID DRUG REBATE

RECONCILIATION OF STATE INVOICE

PAGE _____ OF _____

COMPANY NAME _____
LABELER CODE _____
QUARTER COVERED _____

LABELER CONTACT _____
PHONE _____
FAX _____

STATE _____
INVOICE NO. _____
DATE _____

PRODUCT/ PACKAGE CODE	PRODUCT NAME	REBATE PER UNIT	ADJUSTED REBATE PER UNIT	UNITS				ADJM CODE	DISP CODE	DOLLARS			
				UNITS INVOICED	ADJUSTED UNITS + or -	LABELER DISPUTED UNITS	UNITS PAID			REBATE AMOUNT INVOICED	INVOICE CORRECTION AMOUNT + or -	WITHHELD INVOICE AMOUNT	REBATE AMOUNT PAID
A	B	C	D	E	F	G	H	I	J	K	L	M	N
TOTALS													

Plus Interest Payment _____
TOTAL REMITTANCE _____

HCFA-304 (Exp. 1/98)
OMB No. 0938-0676

MEDICAID DRUG REBATE
LABELER INSTRUCTIONS
for
RECONCILIATION OF STATE INVOICE
(FORM HCFA-304)

The Medicaid Drug Rebate Reconciliation of State Invoice (ROSI) is the mandatory form developed for use by labelers to uniformly notify and explain the remittance of rebate payments to States for the current quarter. The ROSI report **MUST** accompany each rebate payment made to a State for the current quarter utilization invoice **if**:

1. The labeler is NOT paying, in full, the rebate amount due for the current quarter utilization, i.e., the labeler is disputing any units invoiced; or

2. The State invoice contains zeros (0s) in the RPU field because no dollar figure has been made available via the HCFA tape (due to the labeler's lack of data submittal), **AND** the labeler is remitting, in full, the rebate amount due for the current quarter utilization.

The requirement for completion and submittal of the ROSI has the following exceptions.

1. **If** the State invoice contains zeros (0s) in the rebate per unit (RPU) field where a dollar figure has been made available via the HCFA tape, **AND** the labeler is remitting, in full, the rebate amount due for the current quarter utilization. Labelers MUST, however, return a copy of the State's invoice with the rebate payment in full, and may optionally pen/ink the RPU field on the invoice copy.

2. **If** the State invoice contains zeros (0s) in the RPU field due to HCFA data edits, **AND** the labeler is remitting, in full, the rebate amount due for the current quarter utilization. Labelers MUST, however, make pen/ink changes to the RPU on a copy of the State's invoice and return it with the full remittance.

3. **If** there are no zero (0) RPU amounts reported on the State's invoice, **AND** the labeler is remitting, in full, the rebate amount due for the current quarter utilization. Labelers MUST, however, return a copy of the State's invoice with the rebate payment in full.

✎**NOTE**: Labelers may optionally chose to complete and submit the ROSI each quarter regardless of the exceptions listed above.

The labeler's response to the State invoice (whether it be the ROSI or a returned copy of the invoice, as permitted) MUST be submitted within 30 days of receiving the State's invoice of drug utilization for the current quarter.

The ROSI may be completed and submitted in one of two media, paper or electronic, depending on the needs and capabilities of the labeler. To assist you in developing an automated system for completing the ROSI, an electronic field size listing is attached as Appendix A to these instructions. You must submit the ROSI to the State in the format indicated regardless of the media selected. DO NOT submit additional information on the form itself and DO NOT omit any required information, unless instructed in the data definitions.

The Labeler Data Definitions, Appendix B to these instructions, fully explain the information required for each data element contained on the ROSI. Please refer to these definitions for a complete understanding of the column headings whether completing the ROSI via paper or when developing an electronic media.

Appendix C to these instructions, Adjustment and Dispute Codes, lists the various codes you may enter to explain the reason(s) for any adjustments and/or disputes you are reporting. The codes are generic enough in nature to accommodate any adjustment or dispute which may occur. (This list serves both current quarter reporting and prior quarter reporting (See form HCFA-304a). Codes A-I generally are considered Adjustment Codes, and codes N-W generally are considered Dispute Codes. DO NOT USE any codes other than those listed in Appendix C. The lettering of these codes has been divided as shown to accommodate the addition of any future necessary codes.

You may choose up to a maximum of three codes each for adjustments and disputes per NDC. As a general rule, attach supporting documentation as needed for any code selected to further explain the reason for the adjustment or dispute. You must supply documentation for any code where specifically required on the list.

SPECIFIC INSTRUCTIONS

The ROSI is to be used for response to States' **CURRENT QUARTER UTILIZATION DATA ONLY**. (A separate form, HCFA-304a, Prior Quarter Adjustment Statement (PQAS), has been developed for use by labelers to reconcile State utilization changes for prior quarters, prior disputed units, and prior period adjustments.)

1. The ROSI is designed to be quarter and invoice specific. Therefore, no other data than current quarter data should appear on this form.

2. Using the data definitions, enter the required information for **each** NDC reported on the State invoice for the current quarter. Each column is "lettered" for ease of reference.

3. Enter grand totals for columns E through H, and K through N. The grand total for column N for all NDCs listed, plus any interest being paid with this report, should equal the amount of your remittance to the State for the current quarter.

   However, **IF** you complete and submit a PQAS simultaneously with the ROSI, the amount of your remittance should equal the Total Remittance as shown on the ROSI plus or minus the Total Remittance indicated on the PQAS.

4. Submit the ROSI with your rebate payment to the State for the current quarter.

Examples for Completing the ROSI

Attached as appendix D to these instructions is a condensed sample of the ROSI showing column entries for four examples of reconciling the State invoice for current quarter data. The examples reflect situations such as adjusting the rebate per unit, adjusting the units invoiced, and disputing the units invoiced.

Disclosure Statement

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-0676. The time required to complete this information collection is estimated to average 62 hours per response, including the time to review instructions, searching existing data sources, gather the data needed, and complete and review the information collection. If you have any comments concerning the accuracy of the time estimate or suggestions for improving this form, please write to: HCFA, P.O. Box 26686, Baltimore, Maryland 21207, and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, D.C. 20503.

MEDICAID DRUG REBATE
RECONCILIATION OF STATE INVOICE
ELECTRONIC FORMAT

RECORD 1		
FIELD	**SIZE**	**REMARKS**
Record ID	1	Constant of "1"
Company Name	25	First 25 Positions of Company Name
Labeler Code	5	NDC #1
Quarter Covered	5	QYYYY
Labeler Contact	20	Labeler's Contact Person
Phone	14	Area Code/Phone Number/Ext. of Contact
Fax	10	Labeler's Contact Fax Number
State	2	Two Position Postal Abbreviation
Invoice Number	10	Corresponds to State Invoice Number
Date	8	Date Report was Created

RECORD 2		
FIELD	**SIZE**	**REMARKS**
Record ID	1	Constant of "2"
Labeler Code	5	NDC #1
Product/Package Code	6	NDC #2 and #3
Product Name	10	First 10 Positions of Product Name
Rebate Per Unit	11	99999V999999
Adjusted Rebate Per Unit	11	99999V999999
Units Invoiced	12	999999999V999
Adjusted Units (+/-)	13	9999999999V999
Labeler Disputed Units	12	999999999V999
Units Paid	12	999999999V999
Adjustment Code(s)	3	See HCFA-304, Appendix C
Dispute Code(s)	3	See HCFA-304, Appendix C
Rebate Amount Invoiced	9	9999999V99
Invoice Correction Amount (+/-)	10	99999999V99
Withheld Invoice Amount	9	9999999V99
Rebate Amount Paid	9	9999999V99

RECORD 3		
FIELD	**SIZE**	**REMARKS**
Record ID	1	Constant of "3"
Labeler Code	5	NDC #1
Total Units Invoiced	12	999999999V999
Total Adjusted Units (+/-)	13	9999999999V999
Total Labeler Disputed Units	12	999999999V999
Total Units Paid	12	999999999V999
Total Rebate Amount Invoiced	10	99999999V99
Total Invoice Correction Amt (+/-)	11	999999999V99
Total Withheld Invoice Amount	10	99999999V99
Total Rebate Amount Paid	10	99999999V99
Plus Interest Payment	8	999999V99
Total Remittance	10	99999999V99

MEDICAID DRUG REBATE
RECONCILIATION OF STATE INVOICE
(Form HCFA-304)
LABELER DATA DEFINITIONS

::

DATA ELEMENT NAME: Company Name

DATA DEFINITION: Name of company as it appears on the signed rebate agreement.

SPECIFICATIONS: Alpha-numeric values, first 25 positions of company name, left justified, blank filled.

::

DATA ELEMENT NAME: Labeler Code

DATA DEFINITION: First segment of National Drug Code that identifies the manufacturer, labeler, relabeler, packager, repackager or distributor of the drug.

SPECIFICATIONS: Numeric values only, 5 positions right justified, zero filled; no blanks.

::

DATA ELEMENT NAME: Quarter Covered

DATA DEFINITION: This data element will always be the **current quarter and year**.

SPECIFICATIONS: Numeric values, 5 position field, QYYYY; no blanks

Valid values for Q:

1 = January 1 - March 31
2 = April 1 - June 30
3 = July 1 - September 30
4 = October 1 - December 31

Valid values for YYYY: All four digits of calendar year covered.

::

MEDICAID DRUG REBATE
RECONCILIATION OF STATE INVOICE
(Form HCFA-304)
LABELER DATA DEFINITIONS

::

DATA ELEMENT NAME: Labeler Contact

DATA DEFINITION: Labeler's contact person the State should call if there are questions concerning this report.

SPECIFICATIONS: Alpha-numeric values, 20 positions, left justified, first name and last name separated by 1 blank.

::

DATA ELEMENT NAME: Phone

DATA DEFINITION: Telephone number of labeler's contact person.

SPECIFICATIONS: Alpha-numeric values, 14 positions, area code, phone number, and extension, if needed.

::

DATA ELEMENT NAME: Fax

DATA DEFINITION: Telephone Fax number of labeler's contact person.

SPECIFICATIONS: Alpha-numeric values, 10 positions, area code and phone number.

::

DATA ELEMENT NAME: State

DATA DEFINITION: State postal abbreviation.

SPECIFICATIONS: Alpha values, 2 position field; no blanks

::

MEDICAID DRUG REBATE
RECONCILIATION OF STATE INVOICE
(Form HCFA-304)
LABELER DATA DEFINITIONS

::

DATA ELEMENT NAME: Invoice Number

DATA DEFINITION: Identification number of invoice submitted by the State for the current quarter and associated with this report. If invoice contains no identification number, this field will be blank.

SPECIFICATIONS: Alpha-numeric values, 10 position field, right justified, blank filled.

::

DATA ELEMENT NAME: Date

DATA DEFINITION: Date this report was <u>created</u>. (This date is NOT regarded as the date the report was mailed to the State.)

SPECIFICATIONS: Numeric only values, 8 position field; <u>no blanks</u>.

::

DATA ELEMENT NAME: Product/Package Code (Column A)

DATA DEFINITION: Second and Third segments of National Drug Code.

SPECIFICATIONS: Alpha-numeric values, 6 position field, right justified, zero filled; <u>no blanks</u>.

::

DATA ELEMENT NAME: Product Name (Column B)

DATA DEFINITION: First 10 positions of product name as it appears on the FDA registration form.

SPECIFICATIONS: Alpha-numeric values, 10 positions, left justified; blank filled.

::

MEDICAID DRUG REBATE
RECONCILIATION OF STATE INVOICE
(Form HCFA-304)
LABELER DATA DEFINITIONS

::

DATA ELEMENT NAME: Rebate Per Unit (Column C)

DATA DEFINITION: HCFA-calculated rebate per unit as shown on the State invoice.

SPECIFICATIONS: Numeric values, 11 positions: 5 whole numbers and 6 decimals, right justified. Calculate to seven decimals and round to six. IF NOT AVAILABLE ON THE STATE INVOICE, this field will be zero filled; no blanks.

::

DATA ELEMENT NAME: Adjusted Rebate Per Unit (Column D)

DATA DEFINITION: Rebate per unit **IF** different than the amount entered in the Rebate Per Unit field. (The Adjustment Code field must be annotated.)

SPECIFICATIONS: Numeric values, 11 positions: 5 whole numbers and 6 decimals, right justified. Calculate to seven decimals and round to six; blank filled, if not applicable.

::

DATA ELEMENT NAME: Units Invoiced (Column E)

DATA DEFINITION: This element will always be the State-calculated number of units reimbursed as shown on the invoice.

Please note that, upon completion of the ROSI, this element also acts as a compilation of the three elements which follow it (Adjusted Units, Labeler Disputed Units, and Units Paid).

SPECIFICATIONS: Numeric values, 12 positions: 9 whole numbers and 3 decimals, right justified, zero filled; no blanks.

::

MEDICAID DRUG REBATE
RECONCILIATION OF STATE INVOICE
(Form HCFA-304)
LABELER DATA DEFINITIONS

::

DATA ELEMENT NAME: Adjusted Units (+ or -) (Column F)

DATA DEFINITION: The number of units adjusted preceded by + or -, as a result of one of the following:

1. The actual Units Invoiced is adjusted through correspondence or telephone contact with the State prior to claims processing. (For example, if the actual Units Invoiced is 100,000 but the State agrees with the labeler that the figure should be 10,000 the Adjusted Units will be -90,000.)

2. The actual Units Invoiced is adjusted because an understanding exists between the labeler and the State regarding routine adjustments. For example, rounding of decimals, or unit of measure conversions. Under this circumstance, no verbal contact or written explanation is necessary prior to claims processing.

3. The actual Units Invoiced is adjusted by the labeler because an obvious non-routine error exists but the State has not responded to the labeler's correspondence or telephone call to attempt an agreement of an adjusted number.

The Adjustment Code field must be annotated if Adjusted Units are indicated for any NDCs.

SPECIFICATIONS: Numeric values, preceded by a + or - sign, 13 positions: 9 whole numbers and 3 decimals, right justified, blank filled if not applicable.

::

MEDICAID DRUG REBATE
RECONCILIATION OF STATE INVOICE
(Form HCFA-304)
LABELER DATA DEFINITIONS

::

DATA ELEMENT NAME: Labeler Disputed Units (Column G)

DATA DEFINITION: The number of Units Invoiced being disputed,
OR
The number of the remaining units being disputed after an adjustment has been made.

SPECIFICATIONS: Numeric values, 12 positions: 9 whole numbers and 3 decimals, right justified, zero filled; no blanks.

::

DATA ELEMENT NAME: Units Paid (Column H)

DATA DEFINITION: Labeler-calculated number of units paid for. This is calculated as follows:

Units Invoiced
+ or - any Adjusted Units
- any Labeler Disputed Units

SPECIFICATIONS: Numeric values, 12 positions: 9 whole numbers and 3 decimals, right justified, zero filled; no blanks.

::

DATA ELEMENT NAME: Adjustment Code(s) (Column I)

DATA DEFINITION: Reason(s) labeler has adjusted the rebate per unit or the units invoiced.

SPECIFICATIONS: Alpha values only, 3 positions.
Valid values: Refer to HCFA-304, Appendix C
Maximum: 3 Adjustment Codes per NDC

::

MEDICAID DRUG REBATE
RECONCILIATION OF STATE INVOICE
(Form HCFA-304)
LABELER DATA DEFINITIONS

::

DATA ELEMENT NAME: Dispute Code(s) (Column J)

DATA DEFINITION: Reason(s) labeler is disputing the Units Invoiced or the difference, or any part thereof, of the remaining units after adjustment.

SPECIFICATIONS: Alpha values only, 3 positions.
Valid values: Refer to HCFA-304, Appendix C
Maximum: 3 Dispute Codes per NDC

::

DATA ELEMENT NAME: Rebate Amount Invoiced (Column K)

DATA DEFINITION: State-calculated rebate amount as shown on the invoice.

SPECIFICATIONS: Numeric values, 9 positions: 7 whole numbers and 2 decimals, right justified. If not available, this field will be zero filled; no blanks.

Please note that, upon completion of the ROSI, this element also acts as a compilation of the three elements which follow it (Invoice Correction Amount, Withheld Invoice Amount, and Rebate Amount Paid).

::

DATA ELEMENT NAME: Invoice Correction Amount (+ or -) (Column L)

DATA DEFINITION: Labeler-corrected invoice amount (+ or -) based on any Adjusted Units and/or the Rebate Per Unit or the Adjusted Rebate Per Unit.

SPECIFICATIONS: Numeric values, preceded by a + or - sign, 10 positions: 7 whole numbers and 2 decimals, right justified. If not applicable, this field will be zero filled; no blanks, unless the ROSI is manually completed.

::

MEDICAID DRUG REBATE
RECONCILIATION OF STATE INVOICE
(Form HCFA-304)
LABELER DATA DEFINITIONS

DATA ELEMENT NAME: Withheld Invoice Amount (Column M)

DATA DEFINITION: Amount of Rebate Amount Invoiced being withheld,

OR,

the amount being withheld of the remaining Rebate Amount Invoiced after correction.

SPECIFICATIONS: Numeric values, 9 positions: 7 whole numbers and 2 decimals, right justified. If not applicable, this field will be zero filled; no blanks, unless the ROSI is manually completed.

DATA ELEMENT NAME: Rebate Amount Paid (Column N)

DATA DEFINITION: Amount per NDC that the labeler is remitting to the State for current quarter utilization. This amount is calculated as follows:

Rebate Amount Invoiced
\+ or - any Invoice Correction Amount
\- any Withheld Invoice Amount

SPECIFICATIONS: Numeric values, 9 positions: 7 whole numbers and 2 decimals, right justified; zero filled; no blanks.

DATA ELEMENT NAME: Total Units Invoiced

DATA DEFINITION: Total number of State-calculated units invoiced for all NDCs.

SPECIFICATIONS: Numeric values, 12 positions: 9 whole numbers and 3 decimals, right justified, no blanks.

MEDICAID DRUG REBATE
RECONCILIATION OF STATE INVOICE
(Form HCFA-304)
LABELER DATA DEFINITIONS

::

DATA ELEMENT NAME: Total Adjusted Units (+ or -)

DATA DEFINITION: Total number, + or -, of Adjusted Units for all NDCs.

SPECIFICATIONS: Numeric values, preceded by a + or - sign, 13 positions, 9 whole numbers and 3 decimals, right justified, zero filled; no blanks.

::

DATA ELEMENT NAME: Total Labeler Disputed Units

DATA DEFINITION: Total number of disputed units for all NDCs.

SPECIFICATIONS: Numeric values, 12 positions: 9 whole numbers and 3 decimals, right justified, zero filled; no blanks.

::

DATA ELEMENT NAME: Total Units Paid

DATA DEFINITION: Total number of labeler-calculated units paid for all NDCs.

SPECIFICATIONS: Numeric values, 12 positions: 9 whole numbers and 3 decimals, right justified, zero filled; no blanks.

::

DATA ELEMENT NAME: Total Rebate Amount Invoiced

DATA DEFINITION: Total rebate amount invoiced by the State for all NDCs.

SPECIFICATIONS: Numeric values, 10 positions: 8 whole numbers and 2 decimals, right justified, zero filled; no blanks.

::

MEDICAID DRUG REBATE
RECONCILIATION OF STATE INVOICE
(Form HCFA-304)
LABELER DATA DEFINITIONS

DATA ELEMENT NAME:	Total Invoice Correction Amount (+ or -)
DATA DEFINITION:	The total, + or -, of the Invoice Correction Amount for <u>all</u> NDCs.
SPECIFICATIONS:	Numeric values, preceded by a + or - sign, 11 positions: 8 whole numbers and 2 decimals, right justified, zero filled; <u>no blanks</u>.

DATA ELEMENT NAME:	Total Withheld Invoice Amount
DATA DEFINITION:	Total amount the labeler is withholding for <u>all</u> NDCs.
SPECIFICATIONS:	Numeric values, 10 positions: 8 whole numbers and 2 decimals, right justified, zero filled; <u>no blanks</u>.

DATA ELEMENT NAME:	Total Rebate Amount Paid
DATA DEFINITION:	Total amount of <u>rebate</u> the labeler is remitting to the State for <u>all</u> NDCs for current quarter utilization.
SPECIFICATIONS:	Numeric values, 10 positions: 8 whole numbers and 2 decimals, right justified, zero filled; <u>no blanks</u>.

MEDICAID DRUG REBATE
RECONCILIATION OF STATE INVOICE
(Form HCFA-304)
LABELER DATA DEFINITIONS

::

DATA ELEMENT NAME: Plus Interest Payment

DATA DEFINITION: Total amount of any interest payment the labeler is remitting for the current quarter utilization.

SPECIFICATIONS: Numeric values, 8 positions: 6 whole numbers and 2 decimals, right justified, zero filled; no blanks.

::

DATA ELEMENT NAME: TOTAL REMITTANCE

DATA DEFINITION: The Total Rebate Amount Paid for all NDCs plus any interest payment for the current quarter.

SPECIFICATIONS: Numeric values, 10 positions: 8 whole numbers and 2 decimals, right justified, zero filled; no blanks.

::

ADJUSTMENT/DISPUTE CODES
for
RECONCILIATION OF STATE INVOICE
and/or
PRIOR QUARTER ADJUSTMENT STATEMENT

A. Rebate per unit amount has been revised by labeler and reported as required by HCFA.

B. Labeler has calculated rebate where none was reported by State.

C. Units invoiced adjusted through mutual agreement between labeler/State. DO NOT USE this code for prescription times package size discrepancies.

D. Labeler/State unit discrepancy (e.g., GM vs ML).

E. Labeler/State decimal discrepancy.

F. Converted NDC (e.g., correction to package size).

G. Transferred NDC to another labeler code (documentation required).

H. Utilization change from the State.

I. Rebate per unit amount adjusted through correspondence between labeler/State. USE THIS CODE ONLY when the State has reported a rebate per unit that does not reflect an amount based on pricing data reported by the labeler, and adjustment code A is not applicable.

****

N. Discontinued/Terminated NDC for which the shelf life expired more than one year ago.

O. Invalid/miscoded NDC.

P. State units invoiced exceed expected unit sales. (Attach supporting methodology and data source.)

Q. Utilization/quantity is inconsistent with the number of prescriptions.

R. Utilization/quantity is inconsistent with pharmacy reimbursement levels.

S. Utilization/quantity is inconsistent with State historical trends.

T. Utilization/quantity is inconsistent with lowest dispensable package size.

U. Product not rebate eligible. (Give details.)

V. No record of sales in State. (Attach data source.)

W. Closed out. All disputes settled.

MEDICAID DRUG REBATE

RECONCILIATION OF STATE INVOICE

COMPANY NAME _____ LABELER CONTACT _____ STATE _____

LABELER CODE _____ PHONE _____ INVOICE NO. _____

QUARTER COVERED _(enter current qtr)_ FAX _____ DATE _____

				U	N	I	T	S		D	O	L	L	A	R	S
PRODUCT/ PACKAGE CODE	PRODUCT NAME	REBATE PER UNIT	ADJUSTED REBATE PER UNIT	UNITS INVOICED	ADJUSTED UNITS + or -	LABELER DISPUTED UNITS	UNITS PAID	ADJM CODE	DISP CODE	REBATE AMOUNT INVOICED	INVOICE CORRECTION AMOUNT + or -	WITHHELD INVOICE AMOUNT	REBATE AMOUNT PAID
A	B	C	D	E	F	G	H	I	J	K	L	M	N
Example A	ABC	00000.100000		000001000.000		000000100.000	000000900.000		P	0000100.00		0000010.00	0000090.00
Example B	DEF	00000.150000		000001000.000	-000000050.000	000000000.000	000000950.000	C		0000150.00	-0000007.50		0000142.50
Example C	GHI	00000.050000	00000.030000	000001000.000		000000200.000	000000800.000	A	P	0000050.00	-0000020.00	0000006.00	0000024.00
Example D	JKL	00000.250000	00000.300000	000001000.000	-000000100.000	000000100.000	000000800.000	AC	Q	0000250.00	+0000020.00	0000030.00	0000240.00
TOTALS				000004000.000	-000000150.000	000000400.000	000003450.000			0000550.00	-0000007.50	0000046.00	0000496.50

Example A The State invoiced for 1000 units indicating an RPU of 10 cents and a rebate amount claimed of $100. The manufacturer has no adjustments to the RPU or the number of units invoiced, but does dispute 100 units because the units invoiced exceed expected unit sales.

Explanation of Column Entries The Units Paid is the Units Invoiced (1000) less the Disputed Units (100), or 900 units. The Withheld Invoice Amount is the Disputed Units (100) times the RPU (.10), or $10. The Rebate Amount Paid is the Rebate Amount Invoiced ($100) less the Withheld Invoice Amount ($10), or $90.

Example B The State invoiced for 1000 units indicating an RPU of 15 cents and a rebate amount claimed of $150. The manufacturer has no adjustments to the RPU and does not dispute any units, but does adjust the number of units invoiced downward by 50 as agreed upon via correspondence with the State.

Explanation of Column Entries The Units Paid is the Units Invoiced (1000) less the Adjusted Units (50), or 950 units. The Invoice Correction Amount is the Adjusted Units (50) times the RPU (.15), or $7.50. The Rebate Amount Paid is the Rebate Amount Invoiced ($150) less the Invoice Correction Amount ($7.50), or $142.50.

Example C The State invoiced for 1000 units indicating an RPU of 5 cents and a rebate amount claimed of $50. The manufacturer adjusts the RPU to 3 cents (as reported to HCFA but not yet relayed to the State via HCFA's quarterly tape), does not adjust the number of units, but does dispute 200 units because the units invoiced exceed expected unit sales.

Explanation of Column Entries The Units Paid is the Units Invoiced (1000) less the Disputed Units (-200), or 800 units. The Invoice Correction Amount is the DIFFERENCE between the Rebate Amount Invoiced ($50) and what would have been the Rebate Amount Invoiced based on the Adjusted RPU ($30), or -$20. The Withheld Invoice Amount is the Disputed Units (200) times the Adjusted RPU (.03), or $6. The Rebate Amount Paid is the Rebate Amount Invoiced ($50) less the Invoice Correction Amount (-$20), less the Withheld Invoice Amount ($6), or $24

Example D The State invoiced for 1000 units showing an RPU of 25 cents and a rebate amount claimed of $250. The manufacturer adjusts the RPU to 30 cents (as reported to HCFA but not yet relayed to the State via HCFA's quarterly tape), adjusts the number of units invoiced downward by 100 as agreed upon via correspondence with State, and disputes 100 of the remaining units because utilization is inconsistent with the number of prescriptions.

Explanation of Column Entries The Units Paid is the Units Invoiced (1000) less the Adjusted Units (-100) less the Disputed Units (-100), or 800 units. The Invoice Correction Amount is the DIFFERENCE between the Rebate Amount Invoiced ($250) and what would have been the Rebate Amount Invoiced based on the Adjusted RPU and the Adjusted Units ($270), or +$20. The Withheld Invoice Amount is the Disputed Units (100) times the Adjusted RPU (.30), or $30. The Rebate Amount Paid is the Rebate Amount Invoiced ($250) plus the Invoice Correction Amount (-$20), less the Withheld Invoice Amount ($30), or $240.

PRIOR QUARTER ADJUSTMENT STATEMENT

(PQAS)

PRIOR QUARTER ADJUSTMENT STATEMENT (PQAS)

With the OMB approval of the PQAS (form HCFA-304a), **labelers are required** to reconcile and explain prior quarter actions/payments/credits to States. For all prior quarter adjustment activity, labelers must remit any payment due to States, and/or report and show a credit to a rebate previously paid. These transactions **MUST BE REPORTED** to the State using the Prior Quarter Adjustment Statement, better known as the PQAS.

The PQAS is to be used only:

- to respond to the State's invoice for unit adjustments for prior quarters;
- to report adjustments to prior disputed units; and
- to report adjustments to prior rebate payments as a result of changes in pricing data, i.e., PPAs.

The PQAS form (condensed), including complete instructions (data element definitions, adjustment/dispute code listing, and electronic format), and a sample PQAS (condensed) showing examples of how to complete the form are provided in this Section.

REQUIRED USE OF THE PQAS

The OMB has approved HCFA's request for the collection of the data on the PQAS as well as the form itself. Therefore, **labelers are required** to complete and submit the PQAS whenever one or more of the items listed above occurs.

No additional information may be included on the PQAS and no data element should be omitted unless otherwise instructed by the data definitions.

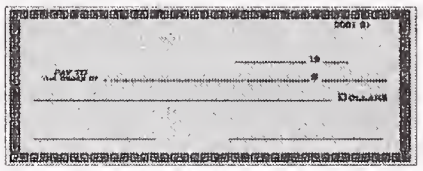
TRANSMITTING THE PQAS

After completion, the PQAS may be submitted to the State in one of two media, paper or electronic, depending on the needs and capabilities of the labeler. An electronic transmission format is provided with the PQAS instructions. Labelers **MUST submit the PQAS data to the State in the required format regardless of the transmission media selected**.

♣ **CLARIFIER**: Portions of this section contain references to URA and RPU. These terms are synonymous in the drug rebate program. URA is mostly used by HCFA when referring to the field on the HCFA State tape containing the unit rebate amount. RPU is used mainly by States and labelers when referring to the field on the Invoice, ROSI, and PQAS containing the rebate per unit. ♣

REVIEWING THE STATE'S UNIT ADJUSTMENT INVOICE

Before remitting any rebate payment for unit adjustments submitted by the State, labelers should review the invoice to determine whether they are in agreement with information reported by the State. For example: Is the RPU correct? Are there any unit discrepancies?



When completing the PQAS, labelers may adjust items reported on the State invoice such as the RPU and the number of adjusted units (only under limited circumstances), and, as a result of the labeler's adjustments to these items, the rebate amount claimed on the invoice. Whenever a labeler reports an adjustment on the PQAS to either the RPU or the number of units, a corresponding adjustment code **MUST** be reported in the space provided. A list of adjustment/dispute codes is attached to the PQAS instructions in this Section.

Labelers **are not permitted**, except under limited circumstances, to change the number of units invoiced by the State. The circumstances under which labelers may adjust the units invoiced are listed below and fully outlined in appendix B to the PQAS instructions. These circumstances lend themselves to an immediate resolution of specific invoice discrepancies, as discussed later in this Section.

The limited circumstances under which a labeler may adjust the number of units reported by the State are:

① Mutual agreement between State/labeler through correspondence/telephone contact.

② Mutual understanding between State/labeler regarding routine adjustments.

③ Obvious non-routine errors; no response by State to labeler's correspondence/telephone call attempting agreement of an adjusted number.

Under no circumstances, other than those listed above, can a labeler adjust the units invoiced by the State. The above circumstances were developed by the Remittance Advice Report Workgroup to assist in reducing the number of units disputed.

Once units are adjusted under the above circumstances, if needed, the remaining units are, of course, subject to dispute. Any adjustments to units after they are officially disputed are made **only by the State** and must be determined using the documentation presented by the labeler and the State under the Dispute Resolution Process. (This process is discussed fully in Section K of this guide.)

IMMEDIATE RESOLUTION OF INVOICE DISCREPANCIES

Items on the unit adjustment invoice for which labelers disagree, may or may not lend themselves to immediate resolution. Immediate resolution can occur when labelers contact the State to discuss what appear to be obvious data errors or entries which the State would most likely agree need correcting. For example:

1. An RPU that does not reflect any data reported to HCFA.
2. Decimal rounding.
3. Unit of measure conversion.

The best way to immediately resolve obvious errors is for labelers to speak directly with the State regarding specific data on the invoice. Immediate resolution also can be accomplished via written correspondence.

In some cases, labelers have an understanding with States which permits the correction of obvious errors, such as decimal rounding, without discussion.

Immediate resolution also can occur even when the disagreement involves the number of adjusted units invoiced. For example, an inadvertent error resulting in an invoice entry of 10,000 units instead of 1,000 units can be immediately resolved with one phone call ☎. This type of resolution reduces and oftentimes eliminates the necessity to dispute the number of units invoiced.

REBATE PER UNIT

Because labelers are responsible for remitting accurate rebate payments, **the current RPU must be applied to the units being paid**. For example, if the State submits a unit adjustment invoice, but the RPU reported is incorrect, or zero, labelers **MUST** use, and report back to the State on the PQAS, the correct RPU. The current RPU for a prior quarter must be applied to all prior quarter adjustment activity, whether it be unit adjustments submitted by the State, adjustments to prior disputed units, or processing of PPAs. Whenever the RPU is corrected on the PQAS, the appropriate adjustment code **must be** annotated in the space provided.

✎**NOTE**: Labelers are required to report to HCFA any pricing data changes in a timely manner. By meeting this obligation, labelers assist HCFA in reporting the most accurate URA to States, which in turn decreases the number of incorrect, or zero, RPUs on the State's invoice. (Pricing data submission requirements are fully discussed at the beginning of this Section.)

The RPU may or may not be considered an immediate resolution item. However, if other items are discussed with the State for immediate resolution, labelers should inform the State that they are making an RPU adjustment.

ADJUSTMENT/DISPUTE CODES

The PQAS instructions contain a listing of various adjustment/dispute codes labelers must enter, as appropriate, for any adjustments and/or disputes reported to the State. These codes are generic enough in nature to accommodate any adjustment or dispute which may occur. Although codes A-I generally are used as adjustment codes, and codes N-W generally are used for disputes, some codes may be appropriate for either situation. Labelers should not use any codes other than those provided on the listing.

The format of the PQAS, paper or electronic, is designed to accommodate a maximum of three (3) codes each for adjustments and disputes per NDC. Generally, labelers should attach supporting documentation, as needed, for any code selected to further explain the reason for the adjustment/dispute. However, labelers MUST supply documentation for any code where specifically required on the listing.

MEDICAID DRUG REBATE

PRIOR QUARTER ADJUSTMENT STATEMENT

(for reconciling unit changes, disputed units, and PPAs)

PAGE _____ OF _____

COMPANY NAME _____
LABELER CODE _____
QUARTER COVERED _____

LABELER CONTACT _____
PHONE _____
FAX _____

STATE _____
INVOICE NO. _____
DATE _____

				UNITS						DOLLARS						
PRODUCT PACKAGE CODE	PRODUCT NAME	ORIGINAL REBATE PER UNIT	CURRENT REBATE PER UNIT	ORIGINAL UNITS INVOICED	CURRENT UNITS TO DATE	PRIOR UNITS PAID	CURRENT UNITS PAID TO DATE	PRIOR UNITS DISPUTED	CURRENT UNITS DISPUTED TO DATE	ORIGINAL AMOUNT INVOICED	REVISED INVOICE AMOUNT	PRIOR AMOUNT PAID	CURRENT AMT PAID TO DATE	AMT PAID THIS TRANS	ADJM CODE	DISP CODE
A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q
TOTALS																

Plus Interest Payment _____
Total Remittance _____

HCFA-304a (Exp. 1/98)
OMB No. 0938-0676

MEDICAID DRUG REBATE
LABELER INSTRUCTIONS
for
PRIOR QUARTER ADJUSTMENT STATEMENT
(FORM HCFA-304a)

The Medicaid Drug Rebate Prior Quarter Adjustment Statement (PQAS) is the mandatory form developed for use by labelers to uniformly reconcile and explain prior quarter actions/payments to States. This form may accompany the current quarter Reconciliation of State Invoice (ROSI) or may be submitted to the State separately. In either case, the PQAS must accompany any rebate payment or payment adjustment made to a State for a prior quarter.

The PQAS may be completed and submitted in one of two media, paper or electronic, depending on the needs and capabilities of the labeler. To assist you in developing an automated system for completing the PQAS, an electronic field size listing is attached as Appendix A to these instructions. You MUST submit the PQAS to the State in the format indicated regardless of the media selected. DO NOT submit additional information on the form itself and DO NOT omit any required information, unless instructed in the data definitions.

The Labeler Data Definitions, Appendix B to these instructions, fully explain the information required for each data element contained on the PQAS. Please refer to these definitions for a complete understanding of the column headings whether completing the PQAS via paper or when developing an electronic media.

Appendix C to these instructions, Adjustment and Dispute Codes, lists the various codes you may enter to explain the reason(s) for any adjustments and/or disputes you are reporting. The codes are generic enough in nature to accommodate any adjustment or dispute which may occur. (This list serves both prior quarter reporting and current quarter reporting.) Codes A-I generally are considered Adjustment Codes, and codes N-W generally are considered Dispute Codes. DO NOT USE any codes other than those listed in Appendix C. The lettering of these codes has been divided as shown to accommodate the addition of any future necessary codes.

You may choose up to a maximum of three codes each for adjustments and disputes per NDC. As a general rule, attach supporting documentation, as needed, for any code selected to further explain the reason for the adjustment or dispute. You must supply documentation for any code where specifically required on the list.

SPECIFIC INSTRUCTIONS

The PQAS is to be used for reporting to States on all PRIOR QUARTER actions, i.e., units changes invoiced by the State, revisions to prior disputed units, and prior period adjustments.

1. The PQAS is designed to be quarter specific. A separate PQAS must be completed for each prior quarter being reconciled.

2. Using the data definitions, enter the required information for each NDC action being reported to the State. Each column is "lettered" for ease of reference.

3. Enter grand totals for columns E through O. The grand total for column O for all NDCs listed, plus any interest being paid with this report, should equal the amount of your remittance to the State for the prior quarters involved.

   NOTE: If you complete and submit the PQAS along with the current quarter ROSI report, the amount of your remittance should equal the Total Remittance as shown on the ROSI, plus or minus the Total Remittance indicated on the PQAS.

4. If an interest payment is indicated on the PQAS a brief explanation must be provided.

5. Submit the completed PQAS with your payment/credit to the State for all prior quarters involved.

Examples for Completing the PQAS

Attached as appendix D to these instructions is a condensed sample of the PQAS showing column entries for five examples of reconciling prior quarter actions. The examples reflect situations such as units changes invoiced by the State, revisions to prior disputed units, and PPAs.

Disclosure Statement

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-0676. The time required to complete this information collection is estimated to average 62 hours per response, including the time to review instructions, searching existing data sources, gather the data needed, and complete and review the information collection. If you have any comments concerning the accuracy of the time estimate or suggestions for improving this form, please write to: HCFA, P.O. Box 26686, Baltimore, Maryland 21207, and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, D.C. 20503.

MEDICAID DRUG REBATE
PRIOR QUARTER ADJUSTMENT STATEMENT
ELECTRONIC FORMAT

RECORD 1		
FIELD	**SIZE**	**REMARKS**
Record ID	1	Constant of "1"
Company Name	25	First 25 Positions of Company Name
Labeler Code	5	NDC #1
Quarter Covered	5	QYYYY
Labeler Contact	20	Labeler's Contact Person
Phone	14	Area Code/Phone No./Ext. of Contact
Fax	10	Labeler's Contact Fax Number
State	2	Two Position Postal Abbreviation
Invoice Number	10	Corresponds to State Invoice Number
Date	8	Date Report was Created

RECORD 2		
FIELD	**SIZE**	**REMARKS**
Record ID	1	Constant of "2"
Labeler Code	5	NDC #1
Product/Package Code	6	NDC #2 and #3
Product Name	10	First 10 Positions of Product Name
Original Rebate Per Unit	11	99999V999999
Current Rebate Per Unit	11	99999V999999
Original Units Invoiced	12	999999999V999
Current Units to Date	12	999999999V999
Prior Units Paid	12	999999999V999
Current Units Paid to Date	12	999999999V999
Prior Units Disputed	12	999999999V999
Current Units Disputed to Date	12	999999999V999
Original Amount Invoiced	9	9999999V99
Revised Invoice Amount	9	9999999V99
Prior Amount Paid	9	9999999V99
Current Amount Paid to Date	9	9999999V99
Amount Paid This Transaction	9	9999999V99
Adjustment Code(s)	3	See HCFA-304a, Appendix C
Dispute Code(s)	3	See HCFA-304a, Appendix C

RECORD 3		
FIELD	**SIZE**	**REMARKS**
Record ID	1	Constant of "3"
Labeler Code	5	NDC #1
Total Original Units Invoiced	12	Total For All NDCs 999999999V999
Total Current Units to Date	12	Total For All NDCs 999999999V999
Total Prior Units Paid	12	Total For All NDCs 999999999V999
Total Current Units Paid to Date	12	Total For All NDCs 999999999V999
Total Prior Units Disputed	12	Total For All NDCs 999999999V999
Total Current Units Disputed to Date	12	Total For All NDCs 999999999V999
Total Original Amount Invoiced	10	Total For All NDCs 99999999V99
Total Revised Invoice Amount	10	Total For All NDCs 99999999V99
Total Prior Amount Paid	10	Total For All NDCs 99999999V99
Total Current Amount Paid to Date	10	Total For All NDCs 99999999V99
Total Amount Paid This Transaction	10	Total For All NDCs 99999999V99
Plus Interest Payment	8	Total For All NDCs 999999V99
Total Remittance	10	Total For All NDCs 99999999V99

MEDICAID DRUG REBATE
PRIOR QUARTER ADJUSTMENT STATEMENT
(Form HCFA-304a)
LABELER DATA DEFINITIONS

::

DATA ELEMENT NAME: Company Name

DATA DEFINITION: Name of company as it appears on the signed rebate agreement.

SPECIFICATIONS: Alpha-numeric values, first 25 positions of company name, left justified, blank filled.

::

DATA ELEMENT NAME: Labeler Code

DATA DEFINITION: First segment of National Drug Code that identifies the manufacturer, labeler, relabeler, packager, repackager or distributor of the drug.

SPECIFICATIONS: Numeric values only, 5 positions right justified, zero filled; no blanks.

::

DATA ELEMENT NAME: Quarter Covered

DATA DEFINITION: This data element will always be a **prior** quarter and year.

SPECIFICATIONS: Numeric values, 5 position field, QYYYY;
no blanks

Valid values for Q:

1 = January 1 - March 31
2 = April 1 - June 30
3 = July 1 - September 30
4 = October 1 - December 31

Valid values for YYYY: All four digits of calendar year covered.

::

MEDICAID DRUG REBATE
PRIOR QUARTER ADJUSTMENT STATEMENT
(Form HCFA-304a)
LABELER DATA DEFINITIONS

::

DATA ELEMENT NAME: Labeler Contact

DATA DEFINITION: Labeler's contact person the State should call if there are questions concerning this report.

SPECIFICATIONS: Alpha-numeric values, 20 positions, left justified, first name and last name separated by 1 blank.

::

DATA ELEMENT NAME: Phone

DATA DEFINITION: Telephone number of labeler's contact person.

SPECIFICATIONS: Alpha-numeric values, 14 positions, area code, phone number, and extension, if needed.

::

DATA ELEMENT NAME: Fax

DATA DEFINITION: Telephone Fax number of labeler's contact person.

SPECIFICATIONS: Alpha-numeric values, 10 positions, area code and phone number.

::

DATA ELEMENT NAME: State

DATA DEFINITION: State postal abbreviation.

SPECIFICATIONS: Alpha values, 2 position field; no blanks

::

MEDICAID DRUG REBATE
PRIOR QUARTER ADJUSTMENT STATEMENT
(Form HCFA-304a)
LABELER DATA DEFINITIONS

::

DATA ELEMENT NAME: Invoice Number

DATA DEFINITION: Identification number of invoice submitted by State and associated with this report. This could be the invoice number for unit changes currently being submitted by the State, or the most recent invoice number for the quarter involved if you are initiating PPAs or revising prior disputed units. If invoice contains no identification number, this field will be blank.

SPECIFICATIONS: Alpha-numeric values, 10 position field, right justified, blank filled.

::

DATA ELEMENT NAME: Date

DATA DEFINITION: Date this report was created. (This date is not regarded as the date the report was mailed to the State.)

SPECIFICATIONS: Numeric only values, 8 position field; no blanks.

::

DATA ELEMENT NAME: Product/Package Code (Column A)

DATA DEFINITION: Second and Third segments of National Drug Code.

SPECIFICATIONS: Alpha-numeric values, 6 position field, right justified, zero filled; no blanks.

::

DATA ELEMENT NAME: Product Name (Column B)

DATA DEFINITION: First 10 positions of product name as it appears on the FDA registration form.

SPECIFICATIONS: Alpha-numeric values, 10 positions, left justified; blank filled.

::

MEDICAID DRUG REBATE
PRIOR QUARTER ADJUSTMENT STATEMENT
(Form HCFA-304a)
LABELER DATA DEFINITIONS

::

DATA ELEMENT NAME: Invoice Number

DATA DEFINITION: Identification number of invoice submitted by State and associated with this report. This could be the invoice number for unit changes currently being submitted by the State, or the most recent invoice number for the quarter involved if you are initiating PPAs or revising prior disputed units. If invoice contains no identification number, this field will be blank.

SPECIFICATIONS: Alpha-numeric values, 10 position field, right justified, blank filled.

::

DATA ELEMENT NAME: Date

DATA DEFINITION: Date this report was created. (This date is not regarded as the date the report was mailed to the State.)

SPECIFICATIONS: Numeric only values, 6 position field; no blanks.

::

DATA ELEMENT NAME: Product/Package Code (Column A)

DATA DEFINITION: Second and Third segments of National Drug Code.

SPECIFICATIONS: Alpha-numeric values, 6 position field, right justified, zero filled; no blanks.

::

DATA ELEMENT NAME: Product Name (Column B)

DATA DEFINITION: First 10 positions of product name as it appears on the FDA registration form.

SPECIFICATIONS: Alpha-numeric values, 10 positions, left justified; blank filled.

::

MEDICAID DRUG REBATE
PRIOR QUARTER ADJUSTMENT STATEMENT
(Form HCFA-304a)
LABELER DATA DEFINITIONS

::

DATA ELEMENT NAME: Original Rebate Per Unit (Column C)

DATA DEFINITION: The rebate per unit that was reported on the original invoice from the State for the quarter involved. This will never change, even if it was "zero."

SPECIFICATIONS: Numeric values, 11 positions: 5 whole numbers and 6 decimals, right justified. Calculate to seven decimals and round to six. IF NOT AVAILABLE ON THE STATE INVOICE, this field will be zero filled; no blanks.

::

DATA ELEMENT NAME: Current Rebate Per Unit (Column D)

DATA DEFINITION: The most recent calculation of the rebate per unit. This may have changed several times, but only enter the most recent. (The Adjustment Code field must be annotated IF this number is different from the Original Rebate Per Unit.)

SPECIFICATIONS: Numeric values, 11 positions: 5 whole numbers and 6 decimals, right justified. Calculate to seven decimals and round to six; blank filled, if not applicable.

::

DATA ELEMENT NAME: Original Units Invoiced (Column E)

DATA DEFINITION: This element will always be the number of units the State first reported on an invoice for the quarter involved. This number will never change.

SPECIFICATIONS: Numeric values, 12 positions: 9 whole numbers and 3 decimals, right justified, no blanks.

::

MEDICAID DRUG REBATE
PRIOR QUARTER ADJUSTMENT STATEMENT
(Form HCFA-304a)
LABELER DATA DEFINITIONS

::

DATA ELEMENT NAME: Current Units To Date (Column F)

DATA DEFINITION: The most recent number of units that was either reported by the State, or agreed upon under one of the circumstances below. This number can be more, less, or the same as the original, and can change from time to time, but always enter the most recent.

Agreed upon units subsequent to State invoicing may be the result of one of the following:

1. The units are adjusted through correspondence or telephone contact with the State.

2. The units are adjusted because an understanding exists between the labeler and the State regarding routine adjustments. For example, rounding of decimals, or unit of measure conversions. Under this circumstance, no verbal contact or written explanation is necessary.

3. The units are adjusted by the labeler because an obvious non-routine error exists but the State has not responded to the labeler's correspondence or telephone call to attempt an agreement of an adjusted number.

The Adjustment Code field must be annotated if the units entered are different from the Original Units Invoiced (Column E) or those currently invoiced for the quarter involved.

SPECIFICATIONS: Numeric values, 12 positions: 9 whole numbers and 3 decimals, right justified, no blanks.

::

MEDICAID DRUG REBATE
PRIOR QUARTER ADJUSTMENT STATEMENT
(Form HCFA-304a)
LABELER DATA DEFINITIONS

::

DATA ELEMENT NAME: Prior Units Paid (Column G)

DATA DEFINITION: The total units paid for this NDC up to, but not including, the date of this report.

SPECIFICATIONS: Numeric values, 12 positions: 9 whole numbers and 3 decimals, right justified, zero filled; no blanks.

::

DATA ELEMENT NAME: Current Units Paid To Date (Column H)

DATA DEFINITION: The total units paid for this NDC, including those paid with this report. This can be more, less, or the same as the Prior Units Paid (Column G).

SPECIFICATIONS: Numeric values, 12 positions: 9 whole numbers and 3 decimals, right justified, zero filled; no blanks.

::

DATA ELEMENT NAME: Prior Units Disputed (Column I)

DATA DEFINITION: The total units disputed for this NDC up to, but not including, the date of this report.

SPECIFICATIONS: Numeric values, 12 positions: 9 whole numbers and 3 decimals, right justified, zero filled; no blanks.

::

DATA ELEMENT NAME: Current Units Disputed To Date (Column J)

DATA DEFINITION: The total units in dispute for this NDC, including those disputed with this report. This can be more, less, or the same as the Prior Units Disputed (Column I).

SPECIFICATIONS: Numeric values, 12 positions: 9 whole numbers and 3 decimals, right justified, zero filled; no blanks.

::

MEDICAID DRUG REBATE
PRIOR QUARTER ADJUSTMENT STATEMENT
(Form HCFA-304a)
LABELER DATA DEFINITIONS

::

DATA ELEMENT NAME: Original Amount Invoiced (Column K)

DATA DEFINITION: The number of ORIGINAL UNITS INVOICED (Column E) times the ORIGINAL REBATE PER UNIT (Column C). This number will never change, even if it is "zero."

SPECIFICATIONS: Numeric values, 9 positions: 7 whole numbers and 2 decimals, right justified, zero filled, no blanks.

::

DATA ELEMENT NAME: Revised Invoice Amount (Column L)

DATA DEFINITION: The number of Current Units To Date (Column F) times the Current Rebate Per Unit (Column D). This can be more, less, or the same as the Original Amount Invoiced (Column K).

SPECIFICATIONS: Numeric values, 9 positions: 7 whole numbers and 2 decimals, right justified, zero filled, no blanks.

::

DATA ELEMENT NAME: Prior Amount Paid (Column M)

DATA DEFINITION: The amount paid for this NDC up to, but not including, the date of this report.

SPECIFICATIONS: Numeric values, 9 positions: 7 whole numbers and 2 decimals, right justified, zero filled, no blanks.

::

MEDICAID DRUG REBATE
PRIOR QUARTER ADJUSTMENT STATEMENT
(Form HCFA-304a)
LABELER DATA DEFINITIONS

::

DATA ELEMENT NAME: Current Amount Paid To Date (Column N)

DATA DEFINITION: The amount paid to date for this NDC, including any amount paid with this report. This can be more, less, or the same as the Prior Amount Paid (Column M), and is the sum of Current Units Paid To Date (Column H) times the Current Rebate Per Unit (Column D).

SPECIFICATIONS: Numeric values, 9 positions: 7 whole numbers and 2 decimals, right justified, zero filled, no blanks.

::

DATA ELEMENT NAME: Amount Paid This Transaction (Column O)

DATA DEFINITION: The amount from Column N less the amount from Column M (Current Amount Paid To Date minus Prior Amount Paid). This amount can be a positive or negative number.

SPECIFICATIONS: Numeric values, 9 positions: 7 whole numbers and 2 decimals, right justified, zero filled, no blanks.

::

DATA ELEMENT NAME: Adjustment Code(s) (Column P)

DATA DEFINITION: Reason(s) labeler has:

1. entered a Current Rebate Per Unit that differs from the Original Rebate Per Unit,

AND/OR

2. has entered a Current Units To Date number that differs from the number of units currently being invoiced for the quarter involved.

SPECIFICATIONS: Alpha values only, 3 positions.
Valid values: Refer to HCFA-304a, Appendix C
Maximum: 3 Adjustment Codes per NDC

::

MEDICAID DRUG REBATE
PRIOR QUARTER ADJUSTMENT STATEMENT
(Form HCFA-304a)
LABELER DATA DEFINITIONS

DATA ELEMENT NAME: Dispute Code(s) (Column Q)

DATA DEFINITION: Reason(s) labeler is:

1. disputing any of the original units or those currently being invoiced for the quarter involved,

AND/OR

2. disputing the difference, or any part thereof, of the remaining units after adjustment.

SPECIFICATIONS: Alpha values only, 3 positions.
Valid values: Refer to HCFA-304a, Appendix C
Maximum: 3 Dispute Codes per NDC

DATA ELEMENT NAME: Total Original Units Invoiced

DATA DEFINITION: Total number of units in Column E for ALL NDCs.

SPECIFICATIONS: Numeric values, 12 positions: 9 whole numbers and 3 decimals, right justified, no blanks.

DATA ELEMENT NAME: Total Current Units To Date

DATA DEFINITION: Total number of units in Column F for ALL NDCs.

SPECIFICATIONS: Numeric values, 12 positions, 9 whole numbers and 3 decimals, right justified, no blanks.

DATA ELEMENT NAME: Total Prior Units Paid

DATA DEFINITION: Total number of units in Column G for ALL NDCs.

SPECIFICATIONS: Numeric values, 12 positions: 9 whole numbers and 3 decimals, right justified, zero filled, no blanks.

MEDICAID DRUG REBATE
PRIOR QUARTER ADJUSTMENT STATEMENT
(Form HCFA-304a)
LABELER DATA DEFINITIONS

::

DATA ELEMENT NAME: Total Current Units Paid To Date

DATA DEFINITION: Total number of units in Column H for ALL NDCs.

SPECIFICATIONS: Numeric values, 12 positions: 9 whole numbers and 3 decimals, right justified, zero filled; no blanks.

::

DATA ELEMENT NAME: Total Prior Units Disputed

DATA DEFINITION: Total number of units in Column I for ALL NDCs.

SPECIFICATIONS: Numeric values, 12 positions: 9 whole numbers and 3 decimals, right justified, zero filled, no blanks.

::

DATA ELEMENT NAME: Total Current Units Disputed To Date

DATA DEFINITION: Total number of units in Column J for ALL NDCs.

SPECIFICATIONS: Numeric values, 12 positions: 9 whole numbers and 3 decimals, right justified, zero filled, no blanks.

::

DATA ELEMENT NAME: Total Original Amount Invoiced

DATA DEFINITION: Total amount in Column K for ALL NDCs.

SPECIFICATIONS: Numeric values, 10 positions: 8 whole numbers and 2 decimals, right justified, zero filled, no blanks.

::

MEDICAID DRUG REBATE
PRIOR QUARTER ADJUSTMENT STATEMENT
(Form HCFA-304a)
LABELER DATA DEFINITIONS

::

DATA ELEMENT NAME: Total Revised Invoice Amount

DATA DEFINITION: Total amount in Column L for ALL NDCs.

SPECIFICATIONS: Numeric values, 10 positions: 8 whole numbers and 2 decimals, right justified, zero filled, no blanks.

::

DATA ELEMENT NAME: Total Prior Amount Paid

DATA DEFINITION: Total amount in Column M for ALL NDCs.

SPECIFICATIONS: Numeric values, 10 positions: 8 whole numbers and 2 decimals, right justified, zero filled, no blanks.

::

DATA ELEMENT NAME: Total Current Amount Paid To Date

DATA DEFINITION: Total amount in Column N for ALL NDCs.

SPECIFICATIONS: Numeric values, 10 positions: 8 whole numbers and 2 decimals, right justified, zero filled, no blanks.

::

DATA ELEMENT NAME: Total Amount Paid This Transaction

DATA DEFINITION: Total amount in Column O for ALL NDCs.

SPECIFICATIONS: Numeric values, 10 positions: 8 whole numbers and 2 decimals, right justified, zero filled, no blanks.

::

MEDICAID DRUG REBATE
PRIOR QUARTER ADJUSTMENT STATEMENT
(Form HCFA-304a)
LABELER DATA DEFINITIONS

::

DATA ELEMENT NAME: Plus Interest Payment

DATA DEFINITION: Total amount of any interest payment the labeler is remitting for the prior quarters contained in this report.

SPECIFICATIONS: Numeric values, 8 positions: 6 whole numbers and 2 decimals, right justified, zero filled, no blanks.

::

DATA ELEMENT NAME: Total Remittance

DATA DEFINITION: The Total Amount Paid This Transaction for all NDCs plus any interest payment for the prior quarters contained in this report.

SPECIFICATIONS: Numeric values, 10 positions: 8 whole numbers and 2 decimals, right justified, zero filled, no blanks.

::

ADJUSTMENT/DISPUTE CODES
for
RECONCILIATION OF STATE INVOICE
and/or
PRIOR QUARTER ADJUSTMENT STATEMENT

A. Rebate per unit amount has been revised by labeler and reported as required by HCFA.

B. Labeler has calculated rebate where none was reported by State.

C. Units invoiced adjusted through mutual agreement between labeler/State. DO NOT USE this code for prescription times package size discrepancies.

D. Labeler/State unit discrepancy (e.g., GM vs ML).

E. Labeler/State decimal discrepancy.

F. Converted NDC (e.g., correction to package size).

G. Transferred NDC to another labeler code (documentation required).

H. Utilization change from the State.

I. Rebate per unit amount adjusted through correspondence between labeler/State. USE THIS CODE ONLY when the State has reported a rebate per unit that does not reflect an amount based on pricing data reported by the labeler, and adjustment code A is not applicable.

****

N. Discontinued/Terminated NDC for which the shelf life expired more than one year ago.

O. Invalid/miscoded NDC.

P. State units invoiced exceed expected unit sales. (Attach supporting methodology and data source.)

Q. Utilization/quantity is inconsistent with the number of prescriptions.

R. Utilization/quantity is inconsistent with pharmacy reimbursement levels.

S. Utilization/quantity is inconsistent with State historical trends.

T. Utilization/quantity is inconsistent with lowest dispensable package size.

U. Product not rebate eligible. (Give details.)

V. No record of sales in State. (Attach data source.)

W. Closed out. All disputes settled.

MEDICAID DRUG REBATE

PRIOR QUARTER ADJUSTMENT STATEMENT

(for reconciling unit changes, disputed units, and PPAs)

APPENDIX D

COMPANY NAME _____ LABELER CONTACT _____ STATE _____

LABELER CODE _____ PHONE _____ INVOICE NO. _____

QUARTER COVERED _____ FAX _____ DATE _____

				U	N	I	T	S		D	O	L	L	A	R	S		
PRODUCT PACKAGE CODE	PRODUCT NAME	ORIGINAL REBATE PER UNIT	CURRENT REBATE PER UNIT	ORIGINAL UNITS INVOICED	CURRENT UNITS TO DATE	PRIOR UNITS PAID	CURRENT UNITS PAID TO DATE	PRIOR UNITS DISPUTED	CURRENT UNITS DISPUTED TO DATE	ORIGINAL AMOUNT INVOICED	REVISED INVOICE AMOUNT	PRIOR AMOUNT PAID	CURRENT AMT PAID TO DATE	AMT PAID THIS TRANS	ADJM CODE	DISP CODE
A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q
Example 1		0.260000	0.160000	700	500	700	500	0	0	182.00	80.00	182.00	80.00	-102.00	AH	
Example 2		0.250000	0.250000	1000	1240	1000	1190	0	50	250.00	310.00	250.00	297.50	47.50	CH	T
Example 3		0.130000	0.030000	1000	900	700	750	300	150	130.00	27.00	91.00	22.50	-68.50	AH	Q
Example 4		0.120000	0.020000	500	500	425	395	75	105	60.00	10.00	51.00	7.90	-43.10	A	P
Example 5		0.300000	0.300000	700	500	425	500	275	0	210.00	150.00	127.50	150.00	22.50	H	W
TOTALS				3900	3640	3250	3335	650	305	832.00	577.00	701.50	557.90	-143.60		

Example 1 State submits a unit change of -200. The original units invoiced were 700 with none disputed. The original RPU of 26 cents has changed to 16 cents.

Column Entries: The Revised Invoice Amount is the number of Current Units (500) times the Current RPU (.16), or $80. The Prior Amount Paid is the Prior Units Paid (700) times the Original RPU (.26), or $182. The Current Amount Paid To Date is the Current Units Paid To Date (500) times the Current RPU (.16), or $80. The Amount Paid This Transaction is the Current Amount Paid To Date ($80) minus the Prior Amount Paid ($182), or -$102.

Example 2 State submits a unit change of +300. The labeler adjusts those units downward by 60 as agreed upon via correspondence with the State, and disputes 50 of the remaining 240 units because quantity is inconsistent with the lowest dispensable package size. The original units invoiced were 1000 with none disputed. The RPU of 25 cents has never changed.

Column Entries: Current Units To Date is the Original Units Invoiced (1000) plus the unit change of 300 minus the 60 units adjusted, or 1240. Current Units Paid To Date is the Current Units To Date (1240) minus the Current Units Disputed (50), or 1190. The Revised Invoice Amount is the Current Units To Date (1240) times the Current RPU (.25), or $310. The Prior Amount Paid is the Prior Units Paid (1000) times the Original RPU (.25), or $250. The Current Amount Paid To Date is the Current Units Paid To Date (1190) times the Current RPU (.25), or $297.50. The Amount Paid This Transaction is the Current Amount Paid To Date ($297.50) minus the Prior Amount Paid ($250), or $47.50.

Example 3 State submits a unit change of -100. The labeler now pays 50 of the prior disputed units. The original units invoiced were 1000 with 300 previously disputed because utilization is inconsistent with the number of prescriptions. The original RPU of 13 cents has changed to 3 cents.

Column Entries: Prior Units Paid is the Original Units Invoiced (1000) minus the Prior Units Disputed (300), or 700. The Current Units Paid To Date is the Prior Units Paid (700) plus 50 of the previously disputed units now being paid, or 750. The Current Units Disputed To Date is the Prior Units Disputed (300) minus the unit change of 100 minus the 50 units previously disputed but now paid, or 150. The Revised Invoice Amount is the Current Units To Date (900) times the Current RPU (.03), or $27. The Prior Amount Paid is the Prior Units Paid (700) times the Original RPU (.13), or $91. The Current Amount Paid To Date is the Current Units Paid To Date (750) times the Current RPU (.03), or $22.50. The Amount Paid This Transaction is the Current Amount Paid To Date ($22.50) minus the Prior Amount Paid ($91), or -$68.50.

Example 4 The RPU of 12 cents has changed to 2 cents. The labeler previously disputed 75 units and now is disputing an additional 30 units because units exceed expected sales. The original units invoiced were 500.

Column Entries: The Current Units To Date is 500 because there is no utilization change reported. The Prior Units Paid is the Original Units Invoiced (500) minus the Prior Units Disputed (75), or 425. The Current Units Paid To Date is the Current Units To Date (500) minus the Current Units Disputed To Date (105), or 395. The Current Units Disputed To Date is the Prior Units Disputed (75) plus the additional 30 units now being disputed, or 105. The Revised Invoice Amount is the Current Units To Date (500) times the Current RPU (.02), or $10. The prior Amount Paid is the Prior Units Paid (425) times the original RPU (.12), or $51. The Current Amount Paid To Date is the Current Units Paid To Date (395) times the Current RPU (.02), or $7.90. The Amount Paid This Transaction is the Current Amount Paid To Date ($7.90) minus the Prior Amount Paid ($51), or -$43.10.

Example 5 The State submits a unit change of -200. The labeler now pays all remaining disputed units. The original units invoiced were 700 with 275 previously disputed. The RPU of 30 cents has never changed.

Column Entries: Because the labeler is paying all remaining disputes, the Current Units Paid To Date is the Same as the Current Units To Date. The Current Units Disputed To Date is zero because the Prior Units Disputed is reduced by the unit change of -200 and further reduced by payment of the 75 previsouly disputed units. The Revised Invoice Amount is the Current Units To Date (500) time the Current RPU (.30), or $150. The Prior Amount Paid is the Prior Units Paid (425) time the Original RPU (.30), or $127.50. The Current Amount Paid To Date is the Current Units Paid To Date (500) time the Current RPU (.30), or $150. The Amount Paid This Transaction is the Current Amount Paid To Date ($150) minus the Prior Amount Paid ($127.50), or $22.50.

HCFA DATA RESPONSIBILITIES

DATA PRE-EDITS

As quarterly pricing data is received by HCFA, it goes through different "pre-edit" edits, depending on the transmission medium used.

☞ **For paper transmission**, data is reviewed prior to data entry to:

1. Make sure that all NDCs on file for the labeler have prices included.

2. Make sure prices look correct and are consistent with Unit Type and prior data submissions.

For example: If a product is an "I" drug, BP must be included with AMP and must be equal to or less than AMP. AMP/BP are checked against Unit Type. If Unit Type is "EA" and AMP equals .02, it would appear that there is a problem. Conversely, if Unit Type is "ML" and AMP equals 125.38, the price would be questioned.

HCFA looks at past quarters' prices for consistency. If the current quarter's price appears similar to previous prices, it would be accepted. If not, HCFA calls ☎ the labeler for a correction. Likewise, if this were the first time for the product, a call ☎ would be made to the labeler.

For corrections to prior quarters, again, consistency would dictate if the change would be made without further research.

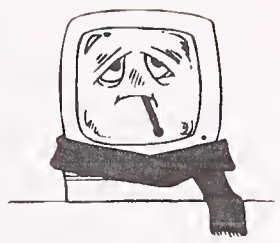
3. Check to assure that multiple package sizes of a product contain the same prices.

4. "Eyeball" Baseline data changes before they are accepted.

Any questionable data justifies a phone call ☎ by HCFA before data is entered.

☞ **When diskettes are received**:

1. They are logged in and run through a computer virus check program. Any diskettes found to contain a virus are cleaned, uploaded to the HCFA mainframe, and run through the same edit program as the Ordernet electronic transmissions. (See below)



2. A phone call ☎ is made to inform the labeler's technical contact about the virus. HCFA informs the technical contact that if the labeler's next quarter's diskette contains a virus, termination ☹ from the program may be forthcoming.

☞ **Ordernet transmitters** send their data to a designated electronic mailbox. The data in the mailbox:

1. Is polled by the HCFA Data Center at specific intervals, depending on the time of the quarter. During the month immediately after a quarter, the mailbox is polled several times a day. During months 2 and 3, it is generally polled twice a day.

2. Is uploaded and run through an edit program which kicks out records that are incorrectly coded or that have no match on HCFA's MDRI master file.

DATA EDIT REPORTS
(Before and After the URA Calculations)

B E F O R E . . .

When necessary, edit reports are sent to labelers with an introductory letter explaining what to look for and what to do, based on data falling into one of three "alert" messages, as well as data that actually "rejects." Labelers are asked to make corrections and resubmit the data using the same transmission medium used for the original data submission.

The edit report shows messages for both rejected and alerted records. Records that reject will do so for a number of reasons. If a quarterly pricing record rejects, it would be due to:

- ◊ AMP/BP not numeric
- ◊ AMP/BP missing
- ◊ Baseline record not on MDRI (NDC does not exist on HCFA's file)

If a Baseline record rejects, it would be for:

- ◊ Field not within specific range (e.g., DESI not between 2 & 6, Unit Type not valid)
- ◊ Numeric field not numeric
- ◊ Market Date/ FDA Approval Date missing (see explanation below)
- ◊ Baseline AMP missing for Market Date < 10-01-93
- ◊ Baseline change (Correction Flag = "1") with no match on MDRI
- ◊ Baseline addition (Correction Flag = "0"), NDC already exists on MDRI

Market Date/FDA Approval Date reject, additional explanation - **Prior to** the enactment of OBRA '93, Baseline records entered on the MDRI system with blank Market and/or FDA Approval Dates would be accepted and assumed to have been introduced prior to 10-01-90. NDCs introduced after this date were required to have Market Dates only. **OBRA '93 requires** that BOTH Dates be present, Market Date for representation of proper CPI-U for the "creep" calculation, and FDA Approval Date to assure that a drug follows its NDA/ANDA date, **NOT** its new NDC number.

The question was whether HCFA should send every labeler a printout of its entire file, asking that ALL missing dates be filled in, or to continue on with the MDRI file as is, and require that missing dates be filled in as the originals were updated. The decision was to go with the latter. Therefore, when labelers attempt to change a Baseline record, if it is one of those that had blank dates, and they DO NOT fill them in as part of this change record, no matter what field they are changing, the record will reject with the message: **Market/FDA Approval Date(s) missing.** This data must be supplied before any changes are allowed. If this happens to be an old NDC that came on the market prior to the start of the drug rebate program, and labelers can not track down one or both of these dates, the "magical" 09-30-90 date can be entered. This will assure that the CPI-U creep calculation will be performed using OBRA '90 rules, rather than OBRA '93 rules.

Besides rejects, there are several **"Alert"** messages that may show up on a labeler's edit report. These messages are listed below and explained in detail on the following pages.

- ◊ AMP increase more than 10% over last quarter
- ◊ BP greater than AMP
- ◊ DESI change attempted

◊AMP increase more than 10% over last quarter

In an attempt to help find and highlight errors or "possible" errors, an edit was included in the edit processing to flag AMP increases when they are more than 10% greater than last quarter. This helps to find data entry errors and, if caught and corrected in time, get the correct AMP in the file so it can be used in HCFA's calculation of the URA. **This AMP will NOT reject**. If the reported AMP is correct, no further input from the labeler is necessary. It will be included for the URA calculation. Likewise, if the AMP is wrong and not corrected in time, it will also be used for the URA calculation and, unless it causes the URA to be on the 50/50 report, will cause an incorrect URA to be sent to the states. (The 50/50 report is discussed later in this Section.)

◊BP greater than AMP

The definition of BP is that it is the lowest sale price offered for the purchase of a product and, therefore, cannot be higher than any other price for it. AMP, because it is calculated using NET sales dollars, rather than GROSS sales dollars, can, in some instances, be calculated as actually lower than Best Price. If this ever occurs, labelers are to make the BP **EQUAL TO AMP** (i.e., lower the BP) for that quarter. Again, **this record is NOT rejected**; however, labelers should make a correction prior to or with their next quarter's pricing data submission.

◊DESI change attempted

Prior to OBRA '93, HCFA used values of "0" and "1" to designate whether a product was ("1") or was not ("0") a DESI drug. The drug rebate program allowed and paid for drugs regardless of their DESI status. With the enactment of OBRA '93, not only did the program change to **NOT COVER** DESI drugs, but HCFA had to break both DESI and non-DESI drugs into specific categories. The values of "2", "3", and "4" are used for drugs that will be covered by the program; values of "5" and "6" are used for those drugs that are not covered (refer to the Quarterly Pricing Data Definitions in Section F for more specifics).

There was a lot of work done between HCFA and the FDA to assure that HCFA's DESI codes were correct. HCFA also set up a system of updating its DESI codes with FDA records each quarter prior to releasing the URA records to States. Because of this, HCFA had to stop all outside DESI updates to the file. **Therefore, if labelers attempt to change a DESI code, an alert message will be generated and they will be told that the change was NOT made and to change their record back to what it was prior to the attempted change**.

. . . A F T E R

After HCFA's quarterly URA tape is sent to the States, **three** reports are generated. These reports are based on specific pricing problems that can only be detected during HCFA's URA calculation process. The reports are mailed to labelers ASAP; however, submitted changes and corrections to pricing data WILL NOT BE USED to calculate the "correct" URA until the following quarterly tape is sent to the States. HCFA DOES NOT send "interim" URA correction files to States between quarters.

The specific reports generated after the completion of URA calculations are explained below.

Report 1 is "NO QUARTERLY PRICES." For all NDCs that are active, pricing data (AMP, and for "S" and "I" drugs, BP) is required each and every quarter. (Active NDCs are those which have a Market Date equal to or less than the current quarter, and do not have a termination date or the termination date is less than 4 quarters old.) If prices "do not change," labelers MUST report the same price as the previous quarter. If there were no sales for the quarter, labelers MUST report the price from the last quarter there were valid sales.

This report shows all NDCs for which HCFA has received NO pricing data. It may be that data was submitted, but was rejected. This data must be corrected and resubmitted. If labelers fail to report any pricing at all, the labeler's entire NDC list will show on the report. If labelers fail to submit pricing data for TWO CONSECUTIVE quarters, they are subject to termination ☹ from the program.

✎**NOTE:** For all NDCs on this report for the quarter shown, the records sent to States contain zero in the URA field. These zeros are then reported on the State's invoice and labelers must compute their own URA calculations in order to determine the appropriate rebate amount due.

Report 2 is "NO REBATES CALCULATED." This report shows NDCs requiring AMP data for a specific prior quarter. In many cases, it will be for a quarter PRIOR TO the labeler's start date. This is due to changes to the URA "CPI-U creep" calculation brought about by OBRA '93.

For all "S" and "I" drugs with a Market Date AFTER 09-30-90, the URA "CPI-U CREEP" calculation for all quarters 93-4 and forward is NOT performed using the original Baseline AMP and CPI-U. Rather, it is done using the CALCULATED AMP FOR THE FIRST FULL QUARTER FOLLOWING THE QUARTER THE PRODUCT WAS INTRODUCED ON THE MARKET and the CPI-U FOR THE MONTH PRIOR TO THAT QUARTER.

Example

NDC 89898-0110-01 is an "I" drug with a Market Date of April 20, 1992.

(Original) Baseline AMP = .12 (first day of sales AMP or selling price for that day)
Unit Type = ML
(Original) Market Date = 04/20/92
(Original) Baseline CPI-U = 139.3 (March, 92)
Labeler Start Date = 10-01-95
Reporting Quarter = 4-95

REQUIRED FROM LABELER

Calculated AMP for qtr 3-92
(USED AS) (NEW) Baseline AMP = .132453

GENERATED BY HCFA

(NEW) Baseline CPI-U = 140.2 (June, 92)
(NEW) Market Date = 07-01-92

✎**NOTE:** The above three fields DO NOT replace the (original) data submitted by the labeler. Instead, they are used IN PLACE OF them.

For ALL CPI-U creep calculations beginning with 93-4, the (NEW) values are used. The labeler in this example entered the program in the 4th qtr of 1995 and supplied Baseline data and 4-95 AMP/BP prices on this NDC; but, did not supply pricing data for the 3rd quarter of 1992. When this report is generated it will show that the AMP from 3-92 is missing and that URAs, for this NDC, CANNOT be generated by HCFA until it is supplied. (Section H of this guide contains a complete discussion of the URA calculation.)

Also, from time to time, a labeler finds that an NDC that should have been coded as "S" or "I" was incorrectly submitted as an "N." The labeler makes the Baseline change on Drug Category as required, but forgets that all prior quarters now require a BP. This report also lists all quarters for each NDC that needs the BP added.

Report 3 is (what HCFA calls) the "50/50 REPORT." This report lists all NDCs that have a URA FOR THE CURRENT QUARTER that calculates as being MORE THAN 50% (+ or -) different from the prior quarter. The purpose of this report is to highlight pricing errors that occur mostly due to decimal alignment problems or one quarter being priced by unit and the other by package.

HCFA realizes that, due to fluctuations in returns and discounts, generally with seasonal products, "peaks" and "valleys" can and do happen. Time has shown, however, that most NDCs on this report are real and valid errors. For those that are legitimate increases/decreases, HCFA's report shows the URA value at the far right of the line. This assists labelers in paying invoices at the correct URA without having to perform the calculation. For those that are true pricing errors, labelers must calculate the correct URA, remit the rebate to States accordingly, and report the correct AMP/BP data to HCFA **PRIOR TO or WITH** the next quarter's pricing data submission.

✎**NOTE:** The following pages show examples of notices sent to labelers as a result of HCFA's various edit reports.

* * * N O T I C E * * *

Attached is an edit listing of your latest Product/Pricing data submittal. Please review and follow the instructions below.

1.) Review any **ALERT** messages dealing with this quarter's AMP more than 10% greater than the previous quarter's AMP. Check for miscoding or decimal alignment problems.

2.) Review any **ALERT** messages stating that ***BP*** is greater than ***AMP***. If, in a given quarter, an ***AMP*** computes out less than ***BP***, due to large discounts or unusually high level of returns, **ALWAYS LOWER** ***BP*** to be equal to ***AMP***.

3.) There may be **ALERT** messages stating that you attempted to change a **DESI** value. Please remember, once it has been established, the **DESI** code can only be changed **BY THE FDA**. This change **DID NOT** take.

4.) For **"REGULAR REJECTS"**, please follow the message. There is probably either an incorrect or unacceptable value.

5.) For **REJECTS** dealing with **Market** and **FDA Approval Dates**, please remember that their inclusion with the Baseline data became mandatory with OBRA'93.

Corrections ***DUE TO REJECTS*** must be performed using your normal method of data submission. Correcting rejects on the attached listing and returning to us **WILL NOT CORRECT THE ERROR. ALL ERRORS ARE REJECTED BY THE SYSTEM AND MUST BE RESUBMITTED ENTIRELY BY YOU.** AMP and BP corrections, *DUE TO ALERTS ONLY*, may be made on the listing and mailed or FAXed to us.

Please refer to *Section G, pages 2 through 7*, of your Operations Guide for additional information.

If you have any questions, please call me on (410) 786-3314 or Judy Allison on (410) 786-3330. Our FAX is (410) 786-0390.

Vince Powell
Drug Rebate Program

* * * ATTENTION REQUIRED * * *

(NO QUARTERLY PRICING DATA REPORT)

Enclosed is a listing of your drug products for which you did not submit quarterly prices for the calendar quarter shown.

If any of these NDCs have been terminated for more than four quarters, please send us a valid Termination Date. NDCs appearing on this listing either DO NOT contain termination dates or have termination dates less than four quarters old. Please remember that prices are due for four quarters ***BEYOND*** the actual quarter of termination or shelf life.

If this report contains 15 or fewer NDCs, please annotate price or termination date corrections and FAX it using (410) 786-0390 or mail it to:

Medicaid Drug Rebate Program
c/o HCFA/MB/OMS
P.O. Box 26686
Baltimore, Md 21207-0486

Please direct it to the attention of Christene Holmes.

If there are more than 15 NDCs, please submit price/date corrections ***WITH*** or ***BEFORE*** your next quarterly submission using your normal mode of data transmission.

If you have any questions, please refer to the Operations Guide starting on page 8 (section G) or call me on (410) 786-3314 or Judy Allison on (410) 786-3330.

Thank you,

Vince Powell
Drug Rebate Operations
HCFA/MB/OMS

*** ATTENTION REQUIRED ***

(NO REBATES - DATA ERRORS)

When OBRA '93 was enacted, certain values used for Unit Rebate Amount (URA) calculations were changed. For ALL "S" & "I" drugs having a **MARKET DATE** =/> 10-01-90, the 'additional rebate' calculation, for quarters **STARTING WITH 4-93**, is performed using the **CALCULATED** AMP for the first full quarter the product was on the market as the BL/AMP. The BL/CPI-U value is equal to the month prior to this first full quarter. Due to this, you must supply pricing data for a product for a quarter prior to your starting in the Drug Rebate Program.

While calculating URAs for this quarter, those NDCs shown on the attached listing were missing the Pricing data for the specific quarter shown. Please submit this information at your earliest convenience. If there are 15 or fewer NDCs, write them **DIRECTLY** on the listing and FAX (to the attention of Christene Holmes) to (410) 786-0390 or return it to the address below:

Drug Rebate Operations
c/o HCFA/MB/OMS
P. O. Box 26686
Baltimore, Md. 21207-0486

If there are more than 15 NDCs, please submit to us using your normal mode of transmission (diskette or electronic).

If you have any questions, please refer to the Operations Guide starting on page 8 (section G) or call me on (410) 786-3314 or Judy Allison on (410) 786-3330.

Thank you,

Vince Powell
Drug Rebate Operations
HCFA/MB/OMS

*** ATTENTION REQUIRED ***

(50/50 REPORT)

Since the start of the Drug Rebate Program, we have been continually changing and adding edit procedures in order to maintain your pricing data as accurately as possible. To this end, we have added an edit which can cause current quarter Unit Rebate Amount (URA) to be reported to the States as zero, **EVEN THOUGH THE AMP/BP FIELDS WERE SUBMITTED ON TIME!!** This will occur when the URA for the current quarter is calculated as more than 50% different (+ or -) from last quarter.

NDCs identified by this edit have been sent to the States this quarter with zeros in the URA field. Attached, please find a listing of your NDCs that match this scenario. Enough historical data is included (Baseline AMP, Market Date, Last Quarter AMP/BP, etc) for you to evaluate the problem and make corrections where applicable. If pricing is correct, **DO NOT NOTIFY US. NEXT QUARTER, THIS URA WILL BE RECALCULATED AND REPORTED AS A PPA TO THE STATES. USE THE CALCULATED URA AT THE FAR RIGHT COLUMN AND COMPUTE TOTAL REBATE OWED FOR THIS NDC TO BE INCLUDED IN YOUR REBATE TO THE STATES.** If a correction to AMP or BP is necessary, please submit it with or before your next quarterly submission and calculate ***THIS QUARTER'S*** rebate using this correct AMP/BP. Use this CORRECTED URA when completing your rebate to the States.

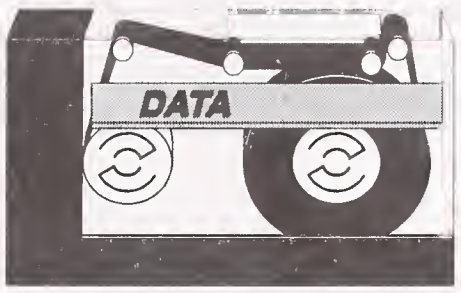
If you have any questions, please refer to the Operations Guide starting on page 8 (section G) or contact me on (410) 786-3314 or Judy Allison on (410) 786-3330.

Thank you,

Vince Powell
Drug Rebate Operations
HCFA/MB/OMS

HCFA STATE TAPE

After the MDRI system is "shut down" and URAs are generated (generally about 45 days after the end of a quarter), a data set on magnetic medium is sent to all State agencies. This tape/cartridge contains several files, two of which are Drug Rebate files.



The first file is the Unit Rebate Master File, which contains:

- ✔ one record for each NDC on HCFA's MDRI Master File (denoted with a correction flag of "0"). Each record contains specific Baseline data needed for identification of the product, e.g., NDC, Product name (first 10 positions only), Unit Type, UPPS, Therapeutic Equivalency Code, Drug Type, Drug Category, and whether it is rebatable by HCFA (DESI Code). This record also includes the URA associated with each NDC for this quarter, or, a value of zero;

- ✔ one record for Baseline changes (denoted with a correction flag of "1"); and

- ✔ one two-record pair of PPAs for all prior quarters where the URA was recalculated this quarter, denoted as "pairs" of "2" [old data] and "3" [new or replacement data]. PPAs are generated when BL/AMP, Market Date, and/or prior quarter AMP or BP are updated. The PPAs are used strickly to verify URA changes to prior quarters that should have already been submitted to States by the labeler.

URA FIELD

→ The correction flag "0" records that have a valid URA included represent NDCs that had pricing data supplied by labelers to HCFA correctly and on time.

→ The correction flag "0" records containing zeros in the URA field, are NDCs where;

1. HCFA did not receive pricing data,
2. the data was received, rejected, and not returned to HCFA in time for inclusion on the quarterly tape, or
3. the pricing data was received by HCFA in time, successfully passed through all edit processing and was included on the MDRI master file, BUT caused the URA to calculate as more than 50% different (+ or -) from the last quarter.

Regardless of which of these three situations occur, the URA field on the HCFA tape will reflect zero, and the States **MUST** report these NDCs on the invoice for all that have utilization. In turn, the labeler must compute the URA and remit the correct rebate amount to the State.

✎**NOTE:** A copy of the URA State tape is sent to First Data Bank and MediSpan. These two companies maintain drug data base files for the vast majority of States. By sending them a copy of each quarterly tape, these companies are assured the opportunity to compare HCFA's data to theirs for continuity and completeness. HCFA **DOES NOT**, however, include actual URAs on these files. The URA data is confidential information released to STATES ONLY. The States are aware of this and take the confidentiality of this data very seriously.

The second file sent on the State tape is the labeler name and address file. This file contains;

- ✓ the labeler code and name,
- ✓ the labeler's effective date in the program,
- ✓ the labeler's termination date, if applicable,
- ✓ the current name, address, and phone number of the labeler's contacts (legal, invoice, and technical), and
- ✓ an active indicator reflecting whether or not a labeler has been reinstated into the program.

States should update the above information from this file to assure that invoices are sent to the correct contact person at the correct address.

It is extremely important that labelers submit all corrections (names/addresses/phone numbers) to HCFA AS SOON AS THEY OCCUR. Otherwise, invoices may be lost, misplaced, received late, etc. These situations can cause a delay in labelers remitting rebates resulting in the possibility of interest liability and other penalties.

There are other files from the Public Health Service that HCFA includes on its quarterly tape as a courtesy for States, but that have no bearing on the Medicaid Drug Rebate program.

ZERO UNIT REBATE AMOUNTS AND "NO MATCH"

The tape/cartridge that HCFA supplies to States each quarter includes one current quarter URA record for each "active" NDC on the MDRI master file. "Active" means that the NDC has a Market Date equal to or less than current quarter, and the Termination Date is either blank or less than four quarters beyond the current quarter.

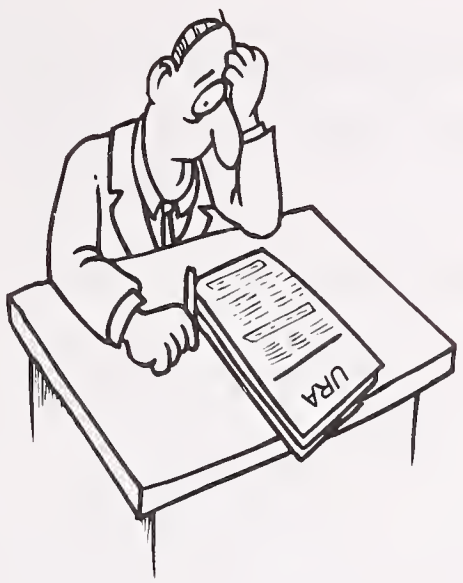
The URA in each record contains either a valid value, or zeros. In either case, States are to use the records to match against their own file. If the State file has an NDC not on the HCFA file, either the NDC is invalid or it is valid but has not yet been established on the HCFA master file. For all non-matches, the State should verify the NDC by either calling the labeler to assure that the NDC is valid, but not yet reported, or by calling HCFA for investigation. In either case, verification will be done to ensure the validity of the NDC. For those NDCs that are valid, inclusion on the invoice is required.

- **If there is a match, and the URA field contains a valid amount**, the State must include the NDC on the invoice reporting all data elements required, including the State's calculation of the rebate amount claimed (the URA X total utilization).

- **If there is a match, and the URA field is zero**, States MUST STILL include the NDC on the invoice showing all data elements required including total utilization, **however**, zeros should be reported in the "Rebate Amount Per Unit" and "Total Rebate Amount Claimed" fields. (DO NOT treat zero URAs on the HCFA tape as nonexistent NDCs.) When URAs are shown as zero on the HCFA tape and reported as such on the State's invoice, labelers are responsible for calculating the rebate amount due using the current URA, and remitting the rebate amount accordingly.

URA

CALCULATION



UNIT REBATE AMOUNT (URA) CALCULATION

There has been much confusion over the years about the URA calculation and what this "CPI-U creep thing" is. Since the enactment of OBRA '93, the confusion has multiplied a hundredfold. The following is an attempt to take some of the mystery out of this calculation and make it more understandable.

The URA calculation is performed in two ways, and **only two ways**.

1. **If a product is in the category of "N"** (non-innovator, multiple source), **the URA is 11% of AMP** (prior to 01-01-94, it was 10%).

2. **If the product category is "S" or "I"** (Single source or Innovator, multiple source), the URA is calculated by using the quarterly AMP and BP, Baseline AMP, and CPI-U values from the month prior to Market Date and month prior to the affected quarter. The "S"/"I" calculation is the same today as it was at the start of the program. The difference is in **WHERE THE VALUES COME FROM AND WHAT VALUES ARE USED (OR, NOT USED, AS IN THE "CAP" VALUES)!!** Based on the Market Date, there are different sets of Baseline values to use for the CPI-U Creep calculation. (These values are described later in this Section.)

✎**NOTE:** Percentages applied to the AMP are set by law.

The URA calculation for "S" and "I" drugs is divided into **two steps**: the "Basic" rebate calculation, and the "Additional" rebate calculation.

STEP 1 - The Basic rebate is equal to **THE GREATER OF** :

a) AMP X the Basic rebate % (e.g., for 1995, % was 15.2)

OR

b) AMP - BP

✎**NOTE**: For 1991, there was a CAP applied to the Basic rebate of 25% of AMP. For 1992, it was 50% of AMP. Beginning with the first quarter, 1993, the CAP was removed.

STEP 2 - The Additional rebate is calculated as follows:

a) Baseline AMP / Baseline CPI-U

b) Answer to a) X quarter CPI-U
This will give a value equal to what the AMP could be raised to based on cost of living.

c) Compare the answer to b) with quarter AMP. If this is EQUAL TO **or** GREATER THAN quarter AMP, there is no additional rebate amount due. If this amount is LESS THAN AMP, subtract this from quarter AMP. This is the Additional rebate owed. ADD this to the Basic rebate URA calculation from step 1 above to arrive at the TOTAL URA for that NDC.

Some examples may make the process for "S" and "I" rebate calculations more understandable. Let's look at the following:

Constants for Each Example

Baseline AMP = .15324
Baseline CPI-U = 149.7 ("New" Market Date = 01-01-95)
Current Quarter = 4th/95
CPI-U = 153.2 (CPI-U from September, 1995)

➤ EXAMPLE 1

AMP = .1548
BP = .151

Step 1 (Basic Rebate)
a) AMP X 15.2% = .0235296
b) AMP - BP = .0038

a) is GREATER than b) thus, the Basic Rebate Amount = .0235296

Step 2 (Additional Rebate)
a) Baseline AMP / Baseline CPI-U = .0010236
b) .0010236 X Current Quarter CPI-U = .1568155
c) answer to b) is GREATER than quarter AMP thus, the Additional Rebate = 0

THEREFORE, THE URA = .023530 (rounded to 6 decimals)

➤ EXAMPLE 2

AMP = .1546
BP = .0983

Step 1 (Basic Rebate)
a) AMP X 15.2% = .0234992
b) AMP - BP = .0563

b) is GREATER than a) thus, the Basic Rebate Amount = .0563

Step 2 (Additional Rebate)
a) Baseline AMP / Baseline CPI-U = .0010236
b) .0010236 X Current Quarter CPI-U = .1568155
c) answer to b) is GREATER than quarter AMP thus,
the Additional Rebate = 0

THEREFORE, THE URA = .0563

➤ EXAMPLE 3

AMP = .2891
BP = .2763

Step 1 (Basic Rebate)
a) AMP X 15.2% = .0439432
b) AMP - BP = .0128

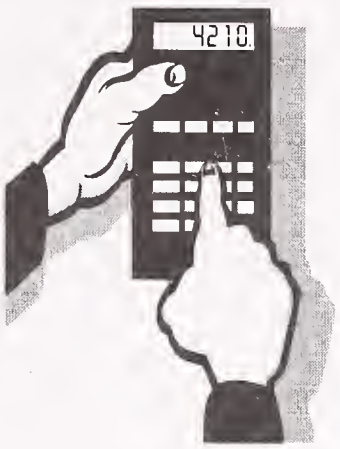
a) is GREATER than b) thus, the Basic Rebate Amount = .0439432

Step 2 (Additional Rebate)
a) Baseline AMP / Baseline CPI-U = .0010236
b) .0010236 X Current Quarter CPI-U = .1568155
c) answer to b) is LESS than AMP thus,
the additional rebate = .1322845
((AMP) .2891 - [b)] .1568155)

THEREFORE, URA = .0439432 + .1322845 = .176228
(rounded to 6 decimals)

When performing URA calculations, replace the CAP, Basic Rebate Percentage, Baseline AMP, and/or Baseline CPI-U with values based on the above scenarios, B U T

☛DO NOT CHANGE THE CALCULATION



Basic Rebate Percentages

Based on the **YEAR the calculation is performed**, the Basic rebate percentages are set by law as follows:

① Quarter 1/91 thru 3/92 = 12.5%
② Quarter 4/92 thru 4/93 = 15.7%
③ Quarter 1/94 thru 4/94 = 15.4%
④ Quarter 1/95 thru 4/95 = 15.2%
⑤ Quarter 1/96 forward = 15.1%

Based on the **YEAR the calculation is performed**, the Basic rebate CAP is set by law as follows:

① 1991 = 25% of AMP
② 1992 = 50% of AMP
③ 1993 and forward = NO CAP

THERE ARE DIFFERENT SETS OF BASELINE VALUES TO USE FOR THE CPI-U CREEP CALCULATION. THESE DIFFERENCES ARE PROVIDED IN BOTH TEXT FORM AND CHART STYLE FOR YOUR CONVENIENCE ON THE FOLLOWING PAGES.

THE DIFFERENCES - WHAT? WHERE? WHEN? HOW? AND WHY?

Based on the **Market Date**, there are different sets of Baseline values to use for the CPI-U Creep calculation. They are as follows:

1. MARKET DATE EQUAL OR LESS THAN 09-30-90

   For ALL quarters from 1-91 thru the present, Baseline AMP equals calculated AMP for quarter 3-90 and is reported with original Baseline data. Baseline CPI-U equals 132.7, which is the CPI-U value for September, 1990.

2. MARKET DATE GREATER THAN 09-30-90 AND LESS THAN 10-01-93

   a. For all quarters from 1-91 thru 3-93, Baseline AMP equals AMP for the first day of the first full month the product is on the market. Baseline CPI-U equals CPI-U for the month preceding the first full month.

   b. For all quarters from 4-93 thru the present, Baseline AMP equals calculated AMP for first quarter **AFTER Market Date**. This is true regardless of whether the Market Date is first day of a quarter, last day of a quarter, or anywhere in between. Baseline CPI-U equals CPI-U **for the month prior to first quarter after Market Date.**

3. MARKET DATE GREATER THAN 09-30-93

   Baseline AMP equals calculated AMP for first quarter **AFTER Market Date**. Baseline CPI-U equals CPI-U for **the month prior to the first quarter after Market Date.**

✎**NOTE**: When performing calculations for 2.a., the CPI-U creep calculation **IS NOT** performed for the quarter the product comes on the market.

When performing calculations for 2.b. or 3., the CPI-U creep calculation **IS NOT** performed for the quarter the product comes on the market NOR the first quarter AFTER the product comes on the market.

THE DIFFERENCES - WHAT? WHERE? WHEN? HOW? WHY?

MARKET DATE EQUAL OR LESS THAN 09-30-90		MARKET DATE GREATER THAN 09-30-90 AND LESS THAN 10-01-93		MARKET DATE GREATER THAN 09-30-93
QTR 1/91 thru present	Baseline AMP=calculated AMP for the quarter 3-90 (and is reported with original Baseline data). Baseline CPI-U=132.7, which is the CPI-U value for September, 1990.	QTR 1/91 - 3/93	Baseline AMP=AMP for the first day of the first full month the product is on the market. Baseline CPI-U=CPI-U for the month preceding the first full month. ✎NOTE: When performing calculations, the CPI-U creep calculation IS NOT performed for the quarter the product comes on the market.	Baseline AMP=calculated AMP for the first quarter AFTER Market Date. Baseline CPI-U=CPI-U for the month prior to the first quarter after Market Date. ✎NOTE: When performing calculations, the CPI-U creep calculation IS NOT performed for the quarter the product comes on the market, NOR the first quarter AFTER the product comes on the market.
		4/93 thru present	Baseline AMP=calculated AMP for the first quarter AFTER Market Date. (This is true regardless of whether the Market Date is the first day of a quarter, last day of a quarter, or anywhere in between.) Baseline CPI-U=CPI-U for the month prior to the first quarter after Market Date. ✎NOTE: When performing calculations, the CPI-U creep calculation IS NOT performed for the quarter the product comes on the market NOR the first quarter AFTER the product comes on the market.	

INTEREST

CALCULATION

INTEREST CALCULATION

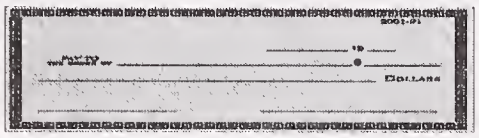
The following is an overview of the interest provisions of the Medicaid Drug Rebate program. For purposes of section V(b) of the National Drug Rebate Agreement, the interest rate, as specified in section 1903(d)(5) of the Act, is used. The interest rate is based on the yield of the weekly 90-day Treasury bill auction rates. The investment yield is considered the bond equivalent rate or the true discount rate.

Auctions of 90-day Treasury bills are generally held each Monday. If Monday is a holiday, the Treasury Department decides whether to hold the auction on the preceding Friday or the following Tuesday. Information on the rates is provided by HCFA to the labelers and State Medicaid agencies periodically in the State Medicaid Director/labeler releases to assure both parties are using the same interest rates in their calculations.

Interest is applied to disputed or unpaid rebate amounts and late rebate payments, but **not to PPAs or dollars associated with State utilization adjustments**. Interest begins accruing on disputed or unpaid amounts 38 calendar days from the date the State mails the utilization data, as evidenced by the postmark by the United States Postal Service, or other common mail carrier, on the envelope (not a postage meter stamp). Note that this is a revision to HCFA's previous policy which specified that interest on unpaid amounts accrues beginning on the 31st day after the labeler receives utilization data from a State. Seven additional days now are given to allow time for receipt by the labeler of the mailing.

This revised policy allows sufficient time for the mailing and receipt of the State utilization data while reducing costs previously associated with return receipt requests. For documentation purposes, States must maintain a record of the date of mailing and labelers must maintain the envelope bearing the postmark from the State.

Interest accrues on the disputed portion of the rebate amount or on the total amount of the late rebate payment for all quarters beginning January 1, 1991 and only stops accruing on the date the check is disbursed.



HCFA considers the date of disbursement to be the date the check is mailed by the labeler.

✎**NOTE: Interest must be collected and may not be disregarded as part of the Dispute Resolution Process by the State or labeler.**

The interest calculation is based on a 365-day year with simple interest applied to the average of the yield of the weekly 90-day Treasury bill auction rates during the period for which interest is charged. (For purposes of this calculation, include the rate for the entire week if the beginning and/or ending date falls within that week.)

To calculate the interest rate to be applied to disputed rebate amounts, use the following formula:

1. Total the yield of each weekly auction of 90-day Treasury bills during the period for which interest will be charged.

2. Divide the total from step 1 by the number of rates to determine the average interest rate.

3. Multiply the average interest rate from step 2 by the unpaid rebate amount to obtain the amount of interest due.

4. Divide the amount of interest due from step 3 by 365 days to obtain the daily amount of interest due.

5. Multiply the daily amount of interest due from step 4 by the number of days that the unpaid rebate amount is outstanding to obtain the total interest due. The first day of interest starts on the 38th day after the State mails the utilization data to the labeler, as evidenced by the postmark.

Interest is applied to disputed or unpaid amounts and late rebate payments but not to PPAs or dollars associated with State utilization adjustments.

EXAMPLE

The State sends a labeler utilization data postmarked 01/25/93, resulting in rebates due totaling $5,400 for the 4th quarter of 1992. Within 30 days after receipt of the data, the labeler pays $4,400 of that amount and disputes the remaining $1,000. Interest starts accruing on 3/4/93, which is the 38th day after the State mailed the data. Subsequently, the labeler decides that the State data are correct and pays the remaining $1,000 by check mailed on 4/2/93.

In this example, interest is accrued for the period 3/4/93 through 4/1/93. The check from the labeler must include the principal of $1,000 plus interest calculated as follows:

AUCTION DATES	AND YIELD RATES	(Obtain yield rates (bond
3/01/93	3.035%	equivalent rates) for
3/08/93	3.043%	period involved.)
3/15/93	3.064%	
3/22/93	3.003%	
3/29/93	3.022%	

- Step 1 - Total the yield rates of each weekly auction of 90-day Treasury Bill. Total: 15.167%

- Step 2 - Divide the total from Step 1 by the number of rates to determine the average interest rate. 15.167% divided by 5 = 3.0334% Average Interest Rate.

- Step 3 - Multiply average interest rate by amount of unpaid rebate. $1,000 x 3.0334% = $30.33 Amount of Interest Due.

- Step 4 - Divide the amount of interest due by 365 days to obtain the amount of interest due per day. $30.33 divided by 365 days = .08310 = Amount of Interest Due Per Day.

- Step 5 - Multiply daily amount of interest due per day by the number of days the unpaid rebate amount is outstanding. $.08309 x 29 days (3/4/93-4/1/93) = $2.41 Total Interest Due.

THEREFORE, THE AMOUNT OF THE CHECK SHOULD BE $1,002.41.

To reiterate, when a labeler pays the State for disputed rebate amounts or late rebate payments, the labeler also must pay all interest due. If a labeler fails to reimburse the State for the interest due, the interest calculations described above will apply to the unpaid balance. The unpaid interest will be treated as principal due, and interest will accrue as of the date the labeler paid the original disputed invoice amount. Interest will continue to accrue on the unpaid balance of the principal for all quarters and stop accruing the date the check is mailed by the labeler.

TOLERANCE THRESHOLD FOR INTEREST

In those instances where the administrative cost of recovering the interest payment exceeds the interest payable to the State, the State may apply the $50 tolerance level per labeler to interest payments. Application of this tolerance is optional for States, i.e., any State may choose to invoice a labeler for interest amounts at or below the tolerance level. In all cases where a State chooses to apply tolerance levels, adequate documentation should be maintained by both the State and the labeler.

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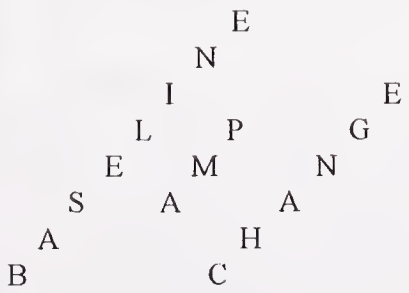
S

Prior Quarter
$ Pricing Changes $
For AMP or BP

PPAs



MARKET DATE
CHANGES
FOR OBRA'93
FORWARD

PRIOR PERIOD ADJUSTMENTS
(PPAs)

Prior period adjustments are URA changes sent to States on the HCFA quarterly tape. These URA changes occur because labelers submit changes to the MDRI pricing file:

1. Whenever there is a change in the AMP and/or BP for a **prior** quarter;
2. When the Baseline AMP changes; or
3. When, for OBRA 1993 URAs, the Market Date changes.

***** Utilization Data Changes Made By States *****
**** ARE NOT PPAs. ****

Any of the above three changes requires an adjustment by the labeler to a previous rebate amount paid based on the utilization submitted for the quarter in question. When labelers send HCFA an AMP or BP price change, or a Baseline change to either BL/AMP or Market Date, the labeler must recalculate the URA for any and all quarters affected by the change. Labelers must use the PQAS to report the recalculated URA, along with all other required data elements, to all affected States. (The PQAS is discussed in Section F of this guide.)

Regardless of when a pricing change is discovered, labelers are required to complete the PQAS using the correct URA, thereby accurately adjusting any prior rebate payments affected by the pricing changes.

HCFA updates the MDRI master file with the labeler's changes and recalculates URAs for all affected quarters. HCFA's next quarterly URA tape to States after receipt of any changes will contain PPA records (type "2" [old] and "3" [new] - pairs only) that the State should use to match to the PQAS submitted by the labeler. Both the tape and the PQAS should match.

There are times when labeler changes effecting PPAs are not received by HCFA in time for inclusion on the current HCFA tape. This situation occurs mostly because labelers discover a problem in BL/AMP, Market Date, or an error in the AMP or BP for a prior quarter subsequent to HCFA sending its quarterly URA tape to the States, and prior to the labeler processing its quarterly payments to the States. When this happens, the labeler's PQAS to the State should reflect the labeler's use of the **current** URA for the quarter in question. However, the State will not receive notification of the PPA change from HCFA until the following quarter.

In the instance where labelers' pricing changes are not received timely by HCFA for inclusion on its quarterly tape, it is necessary for the State to allow two quarters to pass before determining that a match between the HCFA tape and the labeler's PQAS is not present. Pricing changes received subsequent to a quarterly tape issuance will be included on HCFA's next quarterly tape to the States. In the interim, States should accept the data reported by the labeler on the PQAS. Once States have reviewed two consecutive quarterly tapes (if necessary), any discrepancies found between the PPAs on the tape and the labeler's PQAS should be resolved first between the State and the labeler, if possible. Discrepancies which can not be resolved between the parties should be reported by the State to HCFA for resolution.

PPA PROCESSING PRIOR TO AUGUST 1995

Prior to August, 1995, processing of PPAs was the responsibility of the States once PPA information was received via HCFA's quarterly tape. In keeping with section 1927 of the Act and recommendations of the RAR Workgroup implemented by HCFA, the responsibility for processing PPAs was shifted to the labelers. (Statutory language intends that labelers remit rebate payments to the States based on **accurate** pricing data.) Therefore, States were instructed not to include PPAs on their invoices to labelers, but to use the HCFA tape(s) to verify PPA activity reported by the labelers on the PQAS.

Although the current procedure for processing PPAs set forth in this section is in keeping with the Federal statute, some States and labelers were concerned with the shifting of PPA responsibilities as it affects their systems. For example, some States need to maintain an ongoing account of payment adjustments due as a result of labeler pricing changes, and, many labelers want to continue to be able to see what the States believe are PPAs.

To accommodate the needs of both parties, States may attach a PPA listing to their invoices for **informational purposes only**. Dollar amounts associated with this PPA listing should not be part of the dollars claimed on the quarterly invoice.

STATE PPA LISTING V. LABELER PQAS

For those States attaching a PPA listing to their invoice, labelers should match that listing with their own adjustments on the PQAS regarding PPAs. However, please remember that there are times when the State's information received via the HCFA tape will be one quarter behind due to the timeliness of receiving labeler pricing changes for inclusion on the tape. In this instance, although labelers are required to remit rebate payments based on the current URA, the current URA may not match the State's PPA listing until the following quarter's listing.

The same is true on the State's side. The labeler's PQAS annotating PPAs may not match HCFA's quarterly tape until two consecutive quarters have passed. In either case, both parties should be able to verify PPA information within two quarters.

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THIS ➡

DISPUTE RESOLUTION PROCESS

NOT THIS ➡

DISPUTE RESOLUTION PROCESS

After the labeler has reviewed the State's invoice(s) and, as necessary, has attempted an immediate resolution of any invoice item discrepancies (see ROSI and PQAS, Section F of this guide), the labeler must notify the State of any remaining utilization data it wishes to dispute. This notification to the State begins the official dispute resolution process and must be given no later than 38 days after the utilization data is sent by the State.

✎**NOTE:** **All undisputed units must be paid for within the 38-day timeframe. Disputed units accrue interest effective 38 calendar days from the date the State mails the utilization data (postmark of the State's invoice).**

Labelers may dispute **ONLY THE NUMBER OF UNITS** reported by the State. Other items on the invoice for which the labeler disagrees, e.g., RPU, reimbursed amounts, are not subject to dispute under the Dispute Resolution Process. This policy is consistent with the terms of the National Rebate Agreement. While it is recognized that labelers often review Medicaid reimbursement amounts for individual drugs to determine if the respective rebate amounts are appropriate, only the number of units are subject to dispute. Additionally, the Federal statute and the rebate agreement clearly specify the formula for calculating rebate amounts, irrespective of Medicaid reimbursement costs.

Disputes MUST BE:

1. NDC specific; **and**
2. Reason specific.

The labeler's notification to States of disputed units must be accomplished through the use of the ROSI and/or the PQAS forms. Labelers must annotate the appropriate dispute code(s) on these forms and attach any required and/or necessary documentation to support the reason for the dispute.

The Dispute Resolution Process for any given dispute is considered final when the labeler/State have settled all disputed units and corresponding dollar amounts, including interest. Labeler/State settlements proposed on disputed rebate amounts based solely on a dollar amount or a percentage of the disputed dollar amounts involved are unacceptable and **NOT** endorsed by HCFA. States and labelers assume the risk of audits by the Government Accounting Office when settling disputes on any basis other than the number of units. Additionally, States risk the potential of Federal recoupment of FFP when disputes are settled on any basis other than units.

Below are the various stages of the Dispute Resolution Process. This process applies if immediate resolution of utilization data is not accomplished by the 38th day after the State sends its utilization data to the labeler. The Dispute Resolution Process is designed to provide general guidelines and associated time limits. HCFA continues to stress the importance of open communication between labelers and States, and of keeping the HCFA Regional Office Drug Payment Coordinators involved in the process.

PHASE I - EXCHANGE OF DATA TIME PERIOD

Phase I of the process begins after the State receives the labeler's notification of dispute (no later than the 38th day after the State utilization data is sent) and involves a period for both parties to seek resolution of the dispute through exchange of information and informal negotiations.

A. Within 90 Days After Receipt of Labeler's Dispute

State contacts labeler to discuss, by NDC number, units disputed and the reason(s) for the dispute. State presents a report to the labeler of preliminary response to dispute resolution.

B. Within 150 Days After Receipt of Labeler's Dispute

1. State takes steps to resolve questionable data. Labeler requests additional supportive documentation from the State.

State provides:

- Zip-code level data.
- Pharmacy level data, OR opts to conduct a sampling of pharmacy claims.
- Historical trend data.

✎**NOTE:** The type of data provided by the State must match the type of data requested by the labeler.

2. If the parties are unable to resolve differences:

- Labeler requests that the State perform a random sample of pharmacies.
- State requests labeler to validate data used by a third party for the purpose for which the labeler supplied it.

✎**NOTE:** States will ensure that any exchange of data protects the confidentiality requirements of section 1927(b)(3)(D) of the Act. In the case of pharmacy level data, the State may request that the labeler supply its data if confidentiality laws prevent State release of information.

C. Within 240 Days After Receipt of Labeler's Dispute

1. State considers cost effectiveness. If the exchange of information fails to resolve the dispute, and the disputed amount is **BOTH**

   - under $10,000 per labeler code, **AND**
   - under $1,000 per product code of labeler's code (at 9-digit NDC level)

   the State may choose to cease the Dispute Resolution Process.

   ✎**NOTE:** The State maintains discretion to enter into the Dispute Resolution Process in cases that fall below these thresholds.

2. State/labeler complete good faith negotiations. Settlement can be reached based on:

   - State-corrected utilization data, (State should document), OR
   - Valid documentation that other data affecting utilization was accepted.

OR

3. State/labeler are unable to reach an agreement. The State and labeler must proceed to Phase II - Formal Review Process, outlined below.

PHASE II - FORMAL REVIEW

Phase II of the Dispute Resolution Process is initiated when the dispute has not been resolved using the steps in Phase I. The State or the labeler may proceed to phase II if either party has not fulfilled its obligations under any step in phase I of the process.

Within 30 days from the end of Phase I, the State must schedule a hearing that must be conducted no later than one year from the 240th day after the State receives the labeler's dispute. The State and the labeler may continue to attempt resolution of disputes before the hearing is conducted by considering the settlement options described below.

A. Mediation Review - A process in which a mediator assists parties in reaching their own settlement but does not have authority to make a binding decision. Under the Mediation Review:

1. Both parties sign an agreement to mediate.
2. A request for mediation is prepared with a brief statement of the dispute.
3. Both parties agree on how to share mediation expenses.
4. Both parties agree on the selection of a qualified mediator.
5. Mediator has no financial or personal interest in the result of the mediation.
6. Agreement is reached.
7. Both parties sign a settlement agreement.

8. The agreement details the settlement and payment of mediation expenses.
9. The amount in dispute is paid, including interest due.
10. Labeler/State records are documented.

OR

11. Agreement is not reached,
12. Both parties declare in writing that mediation has ended, and

13. Parties pursue Binding Arbitration or State Hearing.

B. Non-Binding Arbitration - A process in which both parties present their case at an informal hearing to a neutral party. Under Non-Binding Arbitration:

1. Both parties agree to participate in arbitration by submitting an informal request to the other party.
2. The parties agree on sharing arbitration fees.
3. Both parties agree on an arbitrator.
4. A decision is reached and both parties sign a settlement agreement.

5. The agreement details the settlement and payment of arbitration fees.
6. The final decision is subject to confirmation at a higher State agency level.
7. The amount in dispute is paid, including interest.
8. Labeler/State records are documented.

OR

9. Agreement is not reached,
10. Parties agree on sharing arbitration fees, and

11. Parties pursue Binding Arbitration or State Hearing.

C. Binding Arbitration - A process in which a dispute is submitted to one or more impartial persons for a final and binding decision. Under Binding Arbitration:

1. Both parties agree to participate in arbitration.
2. Both parties agree on an arbitrator or panel.
3. An arbitrator could be a panel of individuals agreed upon by the State agency and labeler.
4. An arbitrator could be an independent arbitration association, e.g., the American Arbitration Association.
5. Settlement is agreed to by both parties.
6. An award is submitted by the arbitrator stating the relief and arbitration fees.

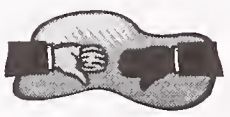
7. If arbitration panel consists of more than one arbitrator the majority decision is binding.

D. Administrative Review - Upon request by either party for a hearing, an administrative review is conducted by an impartial individual or panel appointed or hired as a Hearing Officer to facilitate settlement. This review occurs while the State hearing date is being scheduled. If agreement is reached, the State hearing is canceled. Under an Administrative Review:

1. State requests date for a State hearing.
2. Administrative Review is scheduled prior to the hearing.
3. A Hearing Officer is appointed for the Administrative Review.
4. Settlement is reached at the Administrative Review level.
5. The amount in dispute is paid, including interest due.
6. Settlement is documented.
7. The request for a State hearing is canceled.

OR

8. An agreement is not reached at the Administrative Review level, and
9. Both parties proceed to a State hearing which was scheduled prior to the Administrative Review.



E. State Hearing

A State Hearing must be conducted no later than one year from the 240th day after the State receives the labeler's dispute. The State will make available its State hearing mechanism as defined in the statute and State law. Under the State Hearing process:

1. A hearing is held.
2. A decision is rendered.
3. The dispute is resolved.
4. The amount in dispute is paid, including interest due.
5. Records are documented.

OPTIONAL ALTERNATIVES TO DISPUTE RESOLUTION

The following options fall outside the Dispute Resolution Process, however, the National Drug Rebate Agreement provides these options as an alternative States may pursue after receipt of the labeler's notice of dispute.

1. If the labeler and the State are unable to resolve the dispute, the State may schedule an administrative hearing or tentatively schedule a hearing.

2. If the labeler and the State agree on a resolution and the labeler pays the disputed amount but not the interest due, the State tracks the interest due and follows up with labeler. **Interest begins accruing on the unpaid interest**.

AUDITS

Phase I of the Dispute Resolution Process describes the type of data labelers may request and States may provide in an attempt to resolve a dispute. Excluded from this level of the dispute process is audits, i.e, fraudulent claims and claims level data requests. An audit may be pursued at any time throughout the Dispute Resolution Process.

CLAIMS DATA AUDITS

1. When the labeler requests an audit of State utilization data, the State, with appropriate labeler input, develops mutually agreeable audit procedures.

2. When the labeler requests pharmacy claims level data:

   a. The State agrees to audit the pharmacy.
   b. The State has an independent third party audit the pharmacy.
   c. Payment for audit fees is determined by both parties.

3. When the audit indicates that either State utilization was greater or less than previously specified, or information is inaccurate:

   a. Adjustments are made to the number of units and the corresponding rebate amounts.
   b. The dispute is resolved.

4. After the audit is performed and the State and labeler remain in dispute:

   a. The dispute is not resolved.
   b. Parties proceed to Phase II of the Dispute Resolution Process.

TERMINATION

TERMINATION
FROM THE
MEDICAID DRUG REBATE PROGRAM

All States, except those covering Medicaid drugs under a capitated program, **are required** by section 1927 of the Act to participate in the Medicaid Drug Rebate Program. States can not be terminated from the program, but may be exempt, or become exempt, from the program depending on the method of Medicaid drug coverage in the State.

As stated in section 1927, in order for States to receive FFP for covered outpatient drugs, labelers must have entered into and have in effect a rebate agreement with the Secretary, i.e., the Health Care Financing Administration. The Medicaid Drug Rebate Agreement and section 1927(b)(4)(B) of the Act describe the circumstances under which a labeler can be terminated from the program. Briefly, a labeler may be terminated from the program for failure to submit quarterly pricing data to HCFA, nonpayment of rebates, and for other good cause. The specifics of the termination process are outlined below.

TERMINATION BY HCFA

A labeler's rebate agreement may be terminated by HCFA for violations of the agreement or for other good cause. If termination action is taken, HCFA will provide the labeler, upon request, with a hearing concerning such termination.

If a labeler is subject to termination for failure to submit quarterly pricing data, HCFA will issue the labeler a standard termination warning letter. This letter specifies that unless the identified missing data is received by HCFA within 30 days of the date of the letter, the labeler will be terminated from the program. The termination, as stated in the letter, is effective for the quarter that begins no earlier than 60 days from the date of the letter. HCFA's termination warning letter is the final measure used to attempt to bring the labeler into compliance with the rebate agreement and obtain missing pricing data. It is issued after repeated telephone requests are unheeded.

If a labeler is subject to termination for reasons other than failure to submit pricing data, a similar termination warning letter describing the reason for termination is issued. This letter sets forth a time period to enable the labeler to correct the problem and also provides an opportunity to request a hearing on the termination action.

TERMINATION APPEAL PROCESS

Section 1927 of the Act provides for a hearing, upon request, if a labeler is subject to termination by HCFA. The termination warning letter to the labeler specifies the hearing request process. If a labeler elects to appeal a termination, such appeal must be in writing and received by HCFA within 45 days of the date of the termination warning letter. The appeal notice should include a copy of HCFA's termination warning letter, clearly indicate the labeler's intent to appeal the termination action, and briefly explain why the termination is believed to be incorrect.

The labeler's written notice of appeal may be hand delivered or mailed to the following address:

Health Care Financing Administration
Center for Medicaid and State Operations
Drug Rebate Program
Mail Stop S3-18-13
7500 Security Boulevard
Baltimore, Maryland 21244

TERMINATION BY THE LABELER

A labeler may terminate its drug rebate agreement for any reason with prior written notice to HCFA.

If a labeler chooses not to automatically renew its drug rebate agreement, the effective date of termination will be the ending date of the term of the agreement provided the labeler gives written notice of intent not to renew the agreement at least 90 days before the end of the current agreement period.

If a labeler chooses to terminate its agreement any time during the agreement period, such termination will be effective the first day of the first calendar quarter beginning 60 days after the labeler's written notice requesting termination.

FINAL TERMINATION

When a termination action (voluntary or involuntary) becomes final, HCFA notifies each State Medicaid agency of the termination, and also, that FFP is not available for the labeler's drug products beginning with the effective date of the termination.

✎**NOTE: Any termination (voluntary or involuntary) from the drug rebate program WILL NOT affect rebates due before the effective date of termination.**

RE-ENTERING THE REBATE PROGRAM

Once terminated, a labeler is prohibited from re-entering the drug rebate program until a period of one calendar quarter has elapsed from the effective date of the termination. To re-enter the rebate program, a labeler must complete and sign a **new** Medicaid Drug Rebate Agreement. Any problems which may have caused a labeler's involuntary termination must be resolved prior to re-entering the program, e.g., any missing pricing data must be submitted.

States do not have the authority to terminate a labeler from the Medicaid Drug Rebate Program. By delegation of the Secretary, HCFA retains the authority to determine when termination action is necessary.

States should advise HCFA of those labelers not paying rebates which fall outside the dispute resolution process, or of any violation of the drug rebate agreement. HCFA will investigate State concerns and determine the appropriate action required.

FORMS

This section of the guide contains copies of all the forms (excluding instructions, etc.) required in the Medicaid Drug Rebate Program. The following is a brief description of these forms.

LABELERS

Form HCFA-367, a, b, and c	Form 367 is used to remit quarterly pricing data to HCFA. Form 367a is contact information, 367b (generally a one-time submittal) is a listing of States with whom the labeler has rebate agreements, and 367c is a data media option form.
Form HCFA-304 (ROSI)	Used to notify and explain the remittance of rebate payments to States for the current quarter.
Form HCFA-304a (PQAS)	Used to reconcile and explain prior quarter actions/payments to States.

STATES

Form HCFA-368	Used to report contact information, and a list (generally a one-time submittal) of labelers with whom the State has rebate agreements.
Form HCFA-R-144 (Invoice)	Used to report utilization data to labelers and HCFA.

✎**NOTE:** Specific information regarding these forms can be found in this guide by referencing the Index under "Forms."

DATE: __/__/____
MM/DD/YYYY

PAPER REPORTING FORMAT
LABELER QUARTERLY PRICING DATA

QUARTERLY REPORT FOR QUARTER ____ CALENDAR YEAR _____

FDA ASSIGNED LABELER CODE _____

PRODUCT CODE	PACKAGE SIZE CODE	DRUG CAT.	THERA. EQ. CODE	DESI IND.	AVERAGE MANUFACTURER PRICE	BEST PRICE	DATE ENTERED MARKET
___/___/___	___/___	___	___/___	___	___/___/___/___.___/___/___/___/___	___/___/___/___.___/___/___/___/___	___/___/___/___/___/___/___/___

BASELINE AMP	TERMINATION DATE	CORR. FLAG	UNIT TYPE	UNITS PER PACKAGE SIZE	FDA APPROVAL DATE
___/___/___/___.___/___/___/___/___	___/___/___/___/___/___/___/___	___	___/___	___/___/___/___/___/___/___.___/___	___/___/___/___/___/___/___/___

PRODUCT NAME ___/___/___/___/___/___/___/

MEDICAID DRUG REBATE AGREEMENT
ENCLOSURE B (PAGE 1 OF 4)
SUPPLEMENTAL DATA SHEET

LABELER CODE (as assigned by FDA)

LABELER NAME (Corporate name associated with labeler code)

LEGAL CONTACT - Person to contact for legal issues concerning the rebate agreement.

NAME OF CONTACT

AREA PHONE NUMBER - PHONE NUMBER EXTENSION

NAME OF CORPORATION

STREET ADDRESS

CITY STATE ZIP CODE

INVOICE CONTACT - Person responsible for processing invoice/utilization data.

NAME OF CONTACT

AREA PHONE NUMBER - PHONE NUMBER EXTENSION

NAME OF CORPORATION

STREET ADDRESS

CITY STATE ZIP CODE

NOTE: This sheet is to be returned with the signed rebate agreement. If more than one labeler code, attach one sheet for each code.

HCFA-367a (Exp. 08/31/00)
OMB No. 0938-0578
Rev. 2/98

MEDICAID DRUG REBATE AGREEMENT
ENCLOSURE B (PAGE 2 OF 4)
SUPPLEMENTAL DATA SHEET

LABELER CODE (as assigned by FDA)

LABELER NAME (Corporate name associated with labeler code)

TECHNICAL CONTACT - Person responsible for sending and receiving data.

NAME OF CONTACT

AREA PHONE NUMBER - EXTENSION

NAME OF CORPORATION

STREET ADDRESS

CITY STATE ZIP CODE

NOTE: This sheet is to be returned with the signed rebate agreement. If more than one labeler code, attach one sheet for each code.

HCFA-367a (Exp. 08/31/00)
OMB No. 0938-0578

Rev. 2/98

MEDICAID DRUG REBATE AGREEMENT
ENCLOSURE B (PAGE 3 OF 4)
SUPPLEMENTAL DATA SHEET

LABELER CODE (as assigned by FDA)

LABELER NAME (Corporate name associated with labeler code)

FOR EACH STATE WITH WHOM THE LABELER HAS SIGNED AN EXISTING REBATE AGREEMENT:

STATE (postal code)	EFFECTIVE DATE (MMDDYYYY)	*ENDING DATE (MMDDYYYY)

Note: This sheet is to be returned with the signed rebate agreement. If more than one labeler code, attach one sheet for each code. If there are more than 20 existing agreements, please make copies of this page.

* Date on which initial termination of agreement occurs.

MEDICAID DRUG REBATE AGREEMENT
ENCLOSURE B (PAGE 4 OF 4)
SUPPLEMENTAL DATA SHEET

/ / / /
LABELER CODE (as assigned by FDA)

/ /
LABELER NAME (Corporate name associated with labeler code)

PLEASE INDICATE YOUR MEDIA PREFERENCE YOU INTEND TO USE FOR TRANSMITTING DATA IDENTIFIED IN APPENDIX A OF THE REBATE AGREEMENT TO THE HEALTH CARE FINANCING ADMINISTRATION. THE INSTRUCTIONS, TECHNICAL SPECIFICATIONS AND MATERIALS APPROPRIATE TO THE OPTION SPECIFIED WILL BE MAILED TO YOU UPON RECEIPT OF YOUR SIGNED AGREEMENT.

☐ **OPTION 1 - <u>TELECOMMUNICATIONS</u>**

Transmit data through telecommunications.
Records formats are attached. Upon election of this option, HCFA will mail additional instructions, including the "Dial In" number of the HCFA electronic mailbox.
(See next pages for Telecommunications format.)

☐ **OPTION 2 - <u>3 ½ " HD diskette</u>**

For PC systems supporting MS/DOS 4.0 or higher.
Upon election of this option, a preprogrammed diskette will be mailed to you, along with instructions.

CHECK **<u>ONLY ONE (1)</u>** OF THE FOLLOWING:

☐ MS/DOS

☐ WINDOWS 3.11

☐ WINDOWS 95

☐ **OPTION 3 - <u>PAPER</u>**

For manufacturers with five or fewer drug products.
The form for submitting data is attached.
(See next pages "Paper Reporting Format")

NOTE: This sheet is to be returned with the signed rebate agreement. If more than one labeler code, attach one sheet for each code.

MEDICAID DRUG REBATE

RECONCILIATION OF STATE INVOICE

COMPANY NAME _____ LABELER CONTACT _____ STATE _____

LABELER CODE _____ PHONE _____ INVOICE NO. _____

QUARTER COVERED _____ FAX _____ DATE _____

PRODUCT/ PACKAGE CODE	PRODUCT NAME	REBATE PER UNIT	ADJUSTED REBATE PER UNIT	U N I T S				ADJM CODE	DISP CODE	D O L L A R S			
				UNITS INVOICED	ADJUSTED UNITS + or -	LABELER DISPUTED UNITS	UNITS PAID			REBATE AMOUNT INVOICED	INVOICE CORRECTION AMOUNT + or -	WITHHELD INVOICE AMOUNT	REBATE AMOUNT PAID
A	B	C	D	E	F	G	H	I	J	K	L	M	N
TOTALS													

Plus Interest Payment _____

TOTAL REMITTANCE _____

HCFA-304 (Exp. 1/98)

OMB No. 0938-0676

M8

MEDICAID DRUG REBATE

PRIOR QUARTER ADJUSTMENT STATEMENT

(for reconciling unit changes, disputed units, and PPAs)

COMPANY NAME _____ LABELER CONTACT _____ STATE _____

LABELER CODE _____ PHONE _____ INVOICE NO. _____

QUARTER COVERED _____ FAX _____ DATE _____

				UNITS						DOLLARS						
PRODUCT PACKAGE CODE	PRODUCT NAME	ORIGINAL REBATE PER UNIT	CURRENT REBATE PER UNIT	ORIGINAL UNITS INVOICED	CURRENT UNITS TO DATE	PRIOR UNITS PAID	CURRENT UNITS PAID TO DATE	PRIOR UNITS DISPUTED	CURRENT UNITS DISPUTED TO DATE	ORIGINAL AMOUNT INVOICED	REVISED INVOICE AMOUNT	PRIOR AMOUNT PAID	CURRENT AMT PAID TO DATE	AMT PAID THIS TRANS	ADJM CODE	DISP CODE
A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q
TOTALS																

Plus Interest Payment _____

Total Remittance _____

HCFA-304a (Exp. 1/98)

OMB No. 0938-0678

MEDICAID DRUG REBATE PROGRAM
STATE AGENCY CONTACT FORM

STATE AGENCY NAME

TECHNICAL CONTACT - Person responsible for sending and receiving data.

NAME OF CONTACT

AREA PHONE NUMBER - EXTENSION

NAME OF FISCAL AGENT (if applicable)

STREET ADDRESS

CITY STATE ZIP CODE

PROGRAM POLICY CONTACT - Person responsible for policy decisions.

NAME OF CONTACT

AREA PHONE NUMBER - EXTENSION

NAME OF FISCAL AGENT (if applicable)

STREET ADDRESS

CITY STATE ZIP CODE

HCFA-368 (Exp. 08/31/00)
OMB No. 0938-0582

Rev. 2/98

M10

MEDICAID DRUG REBATE PROGRAM
STATE AGENCY CONTACT FORM

STATE AGENCY NAME

REBATE CONTACT - Person responsible for invoice and receipt of rebate payments.

NAME OF CONTACT

AREA PHONE NUMBER EXTENSION

NAME OF FISCAL AGENT (if applicable)

STREET ADDRESS

CITY STATE ZIP CODE

HCFA-368 (Exp. 08/31/00)
OMB No. 0938-0582

Rev. 2/98

M10a

MEDICAID DRUG REBATE PROGRAM
STATE AGENCY
SUPPLEMENTAL DATA SHEET

STATE AGENCY NAME

FOR EACH LABELER WITH WHOM THE STATE HAS SIGNED AN EXISTING REBATE AGREEMENT:

LABELER CODE	EFFECTIVE DATE (MMDDYYYY)	*ENDING DATE (MMDDYYYY)

Note: If there are more than 20 existing agreements, please make copies of this page.

* Date on which initial termination of agreement occurs.

HCFA-368 (Exp. 08/31/00)
OMB No. 09380582

Rev. 2/98

DATE: ___/___/____
MM DD YYYY

STATE OF _____
_____ (Medicaid Agency)

Source: State Agencies
Target: Manufacturers

MEDICAID DRUG REBATE INVOICE

Manufacturer: _____
Address: _____
_____
City: _____ State: ___ Zip: _____

STATE CODE: ____ INVOICE NO.: _____
PERIOD COVERED: _____(QYYYY)

NDC Number	Drug Name	Rebate Amount Per Unit	Total Units Reimbursed	Total Rebate Amt. Claimed	No. of Scripts	Total Reimb. Amount	Corr Flag

Late Breaking News

HCFA

PROGRAM

RELEASES

HCFA PROGRAM RELEASES

Since the inception of the Medicaid Drug Rebate Program, HCFA has had an obvious need to communicate with labelers and States on an ongoing basis. Unfortunately, HCFA encounters the same problem disseminating information as States/labelers do when reporting data to each other: **lack of media compatibility**. With approximately 500 labelers in the program and 51 State entities, it is impossible for HCFA to maintain the various systems needed to communicate quickly and efficiently. Therefore, the only uniform mode of communication for the initial notification of information to States and labelers is in the form of hardcopy program releases, sent through the mail.

The releases are written and distributed as needed and provide various types of information, most importantly those regarding policy, technical, and operational aspects of the program. As a part of each release, HCFA provides a Topical Index which alphabetically lists the subjects of discussion in the program releases since mid 1991 and the release number(s) in which those subjects are found. Each release also provides a list of weekly U.S. T-Bill Discount Rates which are used by labelers when calculating interest on past due rebates to States.

HCFA sends its program releases to the technical contact person specified by the State and labeler. We are aware that, in many cases, this person is not responsible for ALL drug rebate program functions. **For this reason, and because the releases contain various aspects of the program, HCFA encourages everyone to share the releases with all personnel involved in the drug rebate program.**

OBTAINING COPIES OF PROGRAM RELEASES

Generally, within a week of issuing a release to either State agencies or drug labelers, HCFA uploads the release to the INTERNET.

For States, labelers, and private individuals with access to the Internet, the program releases are available through HCFA's Home Page at www.hcfa.gov.

✎ **NOTE:** HCFA no longer provides the drug rebate releases for incorporation to the CD-ROM.

Following this page are samples of a State and labeler release.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care Financing Administration

7500 SECURITY BOULEVARD
BALTIMORE MD 21244-1850

AUG 12 1996

NEWS

MEDICAID DRUG REBATE PROGRAM Release No. 23

* * * IMMEDIATE ATTENTION REQUIRED * * *

NOTE TO: All Participating Drug Manufacturers

HANDS-ON TRAINING

In our last release, we requested that you complete a survey regarding hands-on training, if you were interested, where would you like it to be held, when, etc. There was about a 25% response to this survey; Western State companies asked for Denver as a training site, and Eastern State companies favored Baltimore or New Jersey.

Based on the survey, travel allocations, one-site hotel and conference availabilities during "non-peak" periods of the next few quarters, etc., it appears that hands-on training, at least for the present, is going to be shelved. Later this year (around October), the operations training guide will be completed and sent to each of you. Although this is not as good as the guide AND hands-on training, it is the best we can offer at the moment. We hope that training will be available sometime during the first six months of Calendar Year 1997. For more information, please call Vince Powell on (410) 786-3314 or Sue Williams on (410) 786-3334.

CHANGING DRUG CATEGORY FOR SPECIFIC QUARTERS FORWARD

It has come to our attention that a repackager can encounter a situation where the Drug Category of a specific NDC can change from/to "N" and require the URA to be calculated under those rules from that quarter forward, rather than corrected back to the start of the program or Market Date of the product. This situation will occur when the repackager, who has been buying

from the Innovator of the product, and pays rebates based on the "S/I" calculation, begins to buy from a Non-Innovator. The repackager does NOT change NDC numbers for this product; however, he should only (from this quarter forward) be required to pay rebates based on the "N" calculation. Likewise, the repackager should begin paying at the "S/I" calculation level when the reverse is true.

Beginning IMMEDIATELY, if you are a repackager and encounter this situation, Drug Category changes FOR THIS SITUATION ONLY, MUST be documented and mailed or faxed to HCFA FOR MANUAL INPUT. DO NOT submit the Drug Category change through the "regular" process. Doing this will cause the system to "assume" that this is a CORRECTION and will recalculate URAs back as far as product history exists, in turn generating PPAs to the States. If you have any questions, please call Vince Powell on (410) 786-3314. Also, please send these changes to Vince's attention. When faxing, please use (410) 786-0390.

VERMONT REBATE INVOICES

Background

The State of Vermont received approval for a Section 1115 waiver effective on January 1, 1996. Many States, including Vermont, use this 1115 demonstration authority to see if the addition of more State residents to the Medicaid rolls can be done under a capitated payment arrangement without increasing the amount of State and Federal dollars they are already spending. Capitated payment arrangements usually involve a State contracting with one or more Heath Maintenance Organizations (HMOs) or Managed Care Organizations (MCOs) to furnish complete or selected health services to all or part of its Medicaid beneficiaries for a set capitation rate. Generally, if outpatient drug services are included in the capitation rate, the State no longer qualifies to submit rebate invoices for payment.

Vermont elected to maintain its outpatient drug services in a fee-for-service arrangement in order to continue receiving rebates from participating drug labelers. Additionally, they added two new groups of beneficiaries to the State Medicaid rolls. One of these two new groups must pay a large percentage of the prescription costs. This means that the State reimbursement data for selected drugs can result in a lower than expected unit acquisition cost. We are alerting drug companies of this situation so as to avoid additional and unnecessary disputes based on State acquisition cost data.

Current Situation

Invoices from the State of Vermont for the 1-96 calendar quarter contain, in many cases, multiple line items for the same National Drug Codes NDC(s). This was done so that disputes for any of the three classes of Medicaid beneficiaries could be accurately tracked by State personnel. This unannounced format change has proven to be extremely difficult to process by drug labelers with automated systems that can only accommodate one entry per NDC.

Action Plan

Since many drug labelers have paid the 1/96 invoice, Vermont informed HCFA that it will contact the remaining drug labelers to ascertain whether they need the regular format of the invoice in order to generate rebate checks. If the established invoice format is required, the State of Vermont will generate a new, standard rebate invoice format. The clock for computing interest on invoices in this category is to be re-set to the date Vermont sends its new invoice for the 1/96 quarter. Rebate invoices for the 2/96 calendar quarter will be generated using the standard format. Questions concerning this item should be referred to Al Beachley at (410) 786-3276 or Vince Powell at (410) 786-3314.

OTHER ATTACHMENTS

Copies of the topic index and the latest listing of the 90-day treasury bill auction rates for the period of September 5, 1995 through July 29, 1996 are attached.

Please remember to direct your drug rebate questions to a staff member on the listing we provided with release number 18.

Tom McCarthy
for

Sally K. Richardson
Director
Medicaid Bureau

2 Attachments

cc:

All Regional Administrators
All Associate Regional Administrators, Division of Medicaid

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(Revised 1 August 1996)

WEEKLY U.S. T-BILL DISCOUNT RATE

The latest weekly 90-day treasury bill auction rates for October 2, 1995 through July 29, 1996 are:

DATE OF AUCTION	TRUE DISCOUNT RATE
10/02/95	5.504
10/10/95	5.471
10/16/95	5.483
10/23/95	5.376
10/30/95	5.450
11/06/95	5.525
11/13/95	5.599
11/20/95	5.503
11/27/95	5.483
12/04/95	5.450
12/11/95	5.463
12/18/95	5.306
12/26/95	5.054
01/02/96	5.190
01/09/96	5.178
01/16/96	5.170
01/22/96	5.137
01/29/96	5.157
02/05/96	5.025
02/12/96	4.939
02/20/96	4.918
02/26/96	4.987
03/04/96	5.020
03/11/96	5.081
03/18/96	5.155
03/25/96	5.123
04/01/96	5.209
04/08/96	5.164
04/15/96	4.999
04/22/96	5.102
04/30/96	5.135
05/06/96	5.155
05/13/96	5.155
05/20/96	5.164
05/28/96	5.164
06/03/96	5.229
06/10/96	5.299
06/17/96	5.217
06/24/96	5.238
07/01/96	5.258
07/08/96	5.353
07/15/96	5.332
07/22/96	5.279
07/29/96	5.341

DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care Financing Administration

7500 SECURITY BOULEVARD
BALTIMORE MD 21244-1850

AUG 27 1996

MEDICAID DRUG REBATE PROGRAM

Release Number 62

* * * IMMEDIATE ATTENTION REQUIRED * * *

NOTE TO: All State Medicaid Directors

DRUG REBATE DISPUTE RESOLUTION MEETINGS BEGIN IN DENVER

The Drug Rebate staff recently began the expansion of the Dispute Resolution Pilot (DRP) to the Western Consortium in the Denver Regional Office (RO). The first series of meetings involved eight States and four drug manufacturers, and resolved approximately $8 million in rebates formerly under dispute. Additionally, staff were able to facilitate the successful resolution of a particularly sensitive situation between a State and a major drug manufacturer which had been previously stalemated. The participating States and manufacturers unanimously expressed support for the DRP and for HCFA's proactive involvement in dispute resolution under the Medicaid drug rebate program. The Drug Rebate staff will conduct another series of meetings in September, and the DRP is planned to continue through 1997. The expectation is to involve as many Western Consortium States as possible. To that end, we encourage all State Medicaid Directors to consider the value and cost-effectiveness of sending the appropriate staff to future dispute resolution meetings.

The DRP was initially conducted in the Boston RO during 1995 and early 1996. In September, the Medicaid Bureau and Region I coordinators of the DRP plan to wrap-up the Region I pilot, and submit a report to the Administrator on the pilot results. The DRP in Region I resulted in the resolution of millions of dollars formerly in dispute among the six Region I States and approximately thirty drug manufacturers. The results of the first meetings in Denver indicate that similar results can be expected from the Western Consortium efforts. Hopefully, the various State Medicaid programs will be able to allocate funds to their staff so that they will be able to attend future DRP meetings in their localities.

HCFA contacts for the DRP are Mike Keogh (410) 786-5910 and Vince Powell (410) 786-3314 from Central Office, Ray Porter from the Boston RO (617) 565-1260, and Diane Dunstan (303) 844-6149 from the Denver RO.

NEW LABELERS

The following labelers have entered into drug rebate agreements and will join the rebate program on October 1, 1996:

Johnson & Johnson - Merck Consumer Pharmaceuticals Co. (Labeler Code 16837),

ROCAP, Inc. (Labeler Code 62338), and

Ucyclyd Pharma, Inc. (Labeler Code 62592).

DRUG LABELER REINSTATEMENTS

Reed & Carnrick/Division of Block Drug (Labeler Code 00021) has signed a new rebate agreement. Their next period of participation in the drug rebate program will begin on October 1, 1996.

LNK International, Inc. (Labeler Code 50844) has submitted missing drug prices for all quarters and signed a new rebate agreement. Their next period of participation in the drug rebate program will begin on October 1, 1996.

LABELER TERMINATIONS

The following labeler is being terminated effective October 1, 1996 for not responding to our telephone calls concerning the required change for submitting drug pricing data to the Medicaid Drug Rebate program:

Chase Pharmaceutical Company (Labeler 54429).

ATTACHMENTS

Copies of the topic index and the latest listing of the 90-day treasury bill auction rates for the period of January 2, 1996 through August 26, 1996 are attached.

Please remember to direct your drug rebate questions to a staff member on the listing we provided with release number 53.

Dan McCarthy
for

Sally K. Richardson
Director
Medicaid Bureau

2 Attachments

cc:

All State Technical Contacts
All Regional Administrators
All Associate Regional Administrators, Division of Medicaid

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(Revised 23 August 1996)

WEEKLY U.S. T-BILL DISCOUNT RATE

The latest weekly 90-day treasury bill auction rates for January 2, 1996 through August 26, 1996 are:

DATE OF AUCTION	TRUE DISCOUNT RATE
01/02/96	5.190
01/09/96	5.178
01/16/96	5.170
01/22/96	5.137
01/29/96	5.157
02/05/96	5.025
02/12/96	4.939
02/20/96	4.918
02/26/96	4.987
03/04/96	5.020
03/11/96	5.081
03/18/96	5.155
03/25/96	5.123
04/01/96	5.209
04/08/96	5.164
04/15/96	4.999
04/22/96	5.102
04/30/96	5.135
05/06/96	5.155
05/13/96	5.155
05/20/96	5.164
05/28/96	5.164
06/03/96	5.229
06/10/96	5.299
06/17/96	5.217
06/24/96	5.238
07/01/96	5.258
07/08/96	5.353
07/15/96	5.332
07/22/96	5.279
07/29/96	5.341
08/05/96	5.217
08/12/96	5.176
08/19/96	5.197
08/26/96	5.209

GIVE US A CALL

HCFA
DRUG REBATE
DIRECTORY

DROP US A NOTE

HCFA DRUG REBATE PROGRAM

Area Code 410

OPERATIONS

Judy Allison	786-3330
Chris Holmes	786-3328
Vince Powell	786-3314
Linda Sapperstein	786-3317
Sue Williams	786-3334

POLICY

Tamara Bruce	786-1519
Sue Gaston	786-6918
Mike Keogh	786-5910
Larry Reed	786-3325

SYSTEM MAINTENANCE

Aaron Allen (Diskette- DOS,WINDOWS)	786-1119
Kay Alexander	786-0252
(HCFA State tape - unreadable/non-receipt)	

DUR

Altamease Arnold	786-5907
Christina Lyon	786-3332

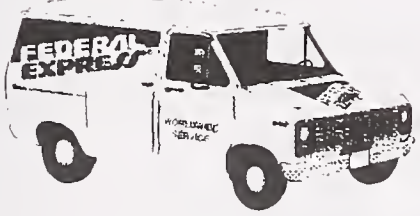
FAX

786-0390 - Operations
786-8534 - Policy

HCFA MEDICAID DRUG REBATE MAILING ADDRESSES

Regular Mail ☞

HCFA, CMSO
Drug Rebate Program
P.O. Box 26686
Baltimore, Maryland 21207



Express Mail ☞

HCFA, CMSO
Drug Rebate Program
Mail Stop S3-19-16
7500 Security Boulevard
Baltimore, Maryland 21244

✎ **NOTE:** PLEASE DO NOT USE the express mail address to send general correspondence to HCFA. The use of this mail stop for general correspondence will delay its delivery to the appropriate individual.

HCFA DRUG REBATE PROGRAM
PRIMARY FUNCTIONS/CONTACT PERSON

Primary Function	Contact Person
Contact Changes (Labelers and States)	Judy Allison Linda Sapperstein
CPI-U Values	Linda Sapperstein Aaron Allen
Data Edit Reports	Judy Allison Vince Powell
Data Submission (Labelers)	Aaron Allen Judy Allison Vince Powell
Data Submission (States)	Vince Powell
Diskette Installation/Problems (DOS and WINDOWS)	Aaron Allen
Dispute Resolution	Mike Keogh Sue Gaston Vince Powell
DUR	Christina Lyon
Federal Upper Limits	Sue Gaston
HIV/AIDS Drugs	Tamara Bruce
Interest Calculation	Sue Gaston
Invoice	Sue Williams
Policy Issues	Tamara Bruce Mike Keogh Sue Gaston
Prior Quarter Adjustment Statement (PQAS)	Sue Williams
Prior Period Adjustments	Aaron Allen Vince Powell
Pricing Data/Product Elements	Aaron Allen Vince Powell
Regulation	Tamara Bruce
Reconciliation of State Invoice (ROSI)	Sue Williams
State Tape (unreadable/non-receipt)	Kay Alexander
T-bill Rates	Aaron Allen
Training Guide	Vince Powell Sue Williams
VHCA/Formulary Regulations	Sue Gaston

HCFA REGIONAL CONSORTIA
DRUG PAYMENT COORDINATORS

As part of an agency-wide reorganization in July of 1997, HCFA's regional offices were restructured into four regional consortia. Below is a breakdown of the consortia and the Drug Payment Coordinator for each. The coordinator for these consortia has responsibility for disseminating all drug program policy, dispute resolution, and Drug Utilization Review for those States within the consortia. (A map of HCFA's regional consortia can be found on page O8 of this guide.)

Please ✎ **NOTE** that the coordinator for the Northeastern Consortium has not been decided. Therefore, please refer to the contact listed for each of the regions within this consortium until further notice.

NORTHEASTERN CONSORTIUM, includes:

- **Boston Region** (Connecticut, New Hampshire, Maine, Massachusetts, Rhode Island, and Vermont)
  Coordinator: Ray Porter
  Telephone: 617-565-1260

- **New York Region** (New Jersey and New York)
  Coordinator: Robert Cochrane
  Telephone: 212-264-3885

- **Philadelphia Region** (Delaware, District of Columbia, Maryland, Pennsylvania, Virginia, and West Virginia)
  Coordinator: Tom Zlakowski
  Telephone: 215-596-4161

SOUTHERN CONSORTIUM, includes:

- **Atlanta Region** (Alabama, Florida, Georgia, Kentucky, Mississippi, North Carolina, South Carolina, and Tennessee)

- **Dallas Region** (Arkansas, Louisiana, New Mexico, Oklahoma, and Texas)

Coordinator: Joe Reeder
Telephone: 214-767-4419

MIDWEST CONSORTIUM, includes:

- **Chicago Region** (Illinois, Indiana, Michigan, Minnesota, Ohio, and Wisconsin)

- **Kansas City Region** (Iowa, Kansas, Missouri, and Nebraska)

Coordinator: Ron Benjamin
Telephone: 312-353-5969

WESTERN CONSORTIUM, includes:

- **Denver Region** (Colorado, Montana, North Dakota, South Dakota, Utah, and Wyoming)

- **San Francisco Region** (Arizona, California, Nevada, and Hawaii)

- **Seattle Region** (Alaska, Idaho, Oregon, and Washington)

Coordinator: Diane Dunstan
Telephone: 303-844-2121 ext. 452

RESERVED

FOR

FUTURE USE

HEALTH CARE FINANCING ADMINISTRATION

REGIONAL CONSORTIA

(A Management Partnership Among HCFA's Regional Offices)

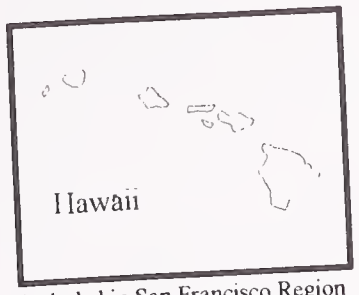
MIDWEST CONSORTIUM
Chicago Region: IL, IN, MI, MN, OH, WI
Kansas City Region: IA, KS, MO, NE

NORTHEASTERN CONSORTIUM
Boston Region : CT, ME, MA, NH, RI, VT
New York Region : NJ, NY, PR, VI
Philadelphia Region: DE, DC, MD, PA, VA, WV

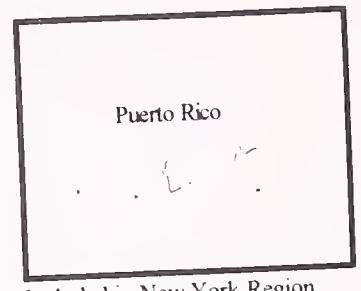
WESTERN CONSORTIUM
Denver Region: CO, MT, ND, SD, UT, WY
San Francisco Region : AZ, CA, NV, HI, U.S. Pacific Territories
Seattle Region: AK, ID, OR, WA

SOUTHERN CONSORTIUM
Atlanta Region: AL, FL, GA, KY, MS, TN, NC, SC
Dallas Region: AR, LA, NM, OK, TX

Included in Seattle Region

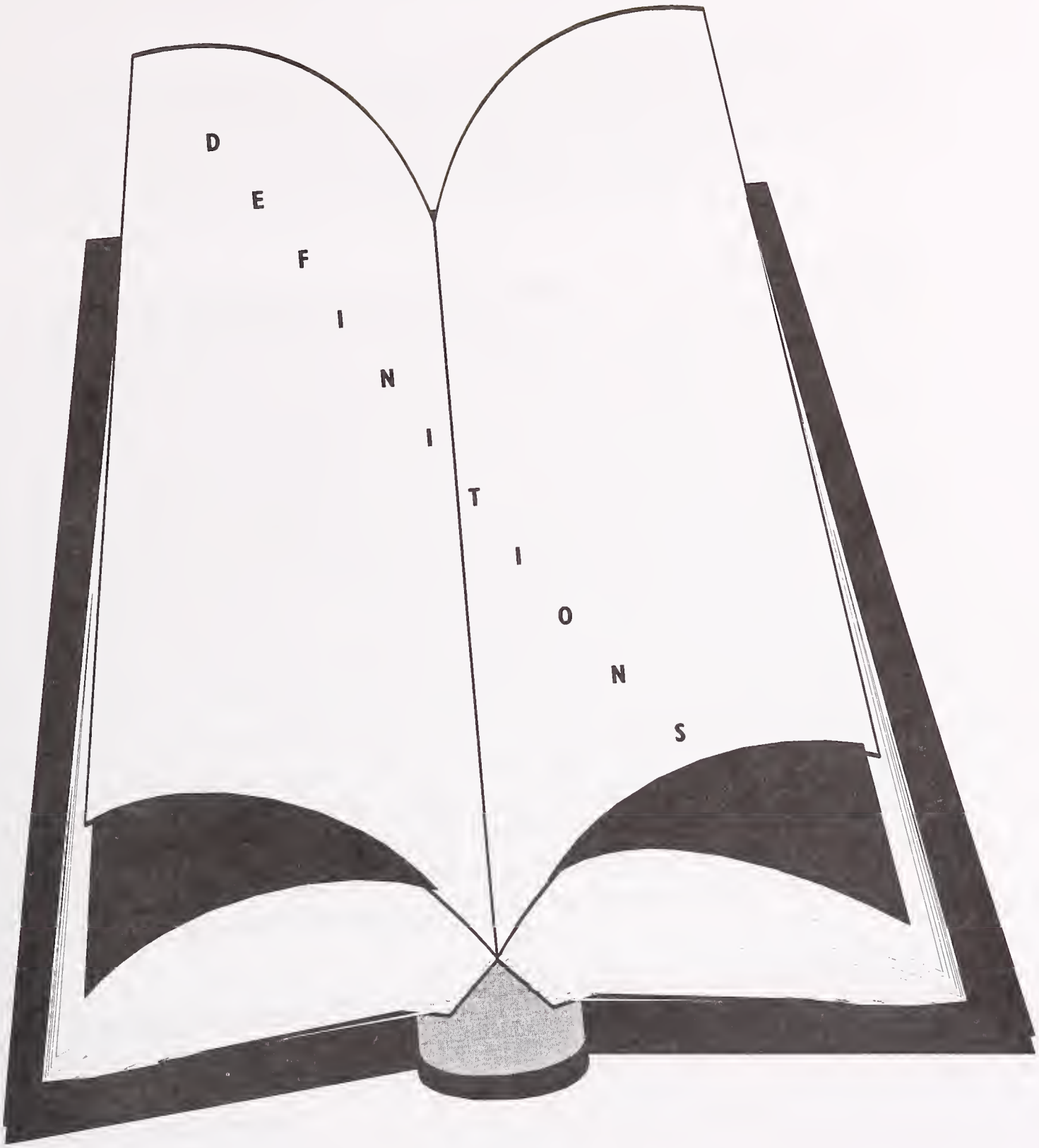


Included in San Francisco Region
Not Shown Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands



Included in New York Region
Not Shown Virgin Islands

July 1997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PROGRAM DEFINITIONS

The following definitions are programmatic and operational in nature. Some definitions were taken from the statute and interpreted herein. Specific data definitions related to reporting requirements, e.g., pricing data, ROSI/PQAS forms, are contained in their respective sections of this guide.

Average Manufacturer Price (AMP) means, with respect to a covered outpatient drug of the labeler for a calendar quarter, the average unit price paid to the labeler for the drug in the States by wholesalers for drugs distributed to the retail pharmacy class of trade (excluding direct sales to hospitals, health maintenance organizations and to wholesalers where the drug is relabeled under that distributor's national drug code number). Federal Supply Schedule prices are not included in the calculation of AMP. AMP includes cash discounts allowed and all other price reductions (other than rebates under section 1927 of the Act), which reduce the actual price paid. It is calculated as a weighted average of prices for all the labeler's package sizes for each covered outpatient drug sold by the labeler during that quarter. Specifically, it is calculated as Net Sales divided by numbers of units sold, excluding free goods (i.e., drugs or any other items given away, but not contingent on any purchase requirements). For Bundled Sales, the allocation of the discount is made proportionately to the dollar value of the units of each drug sold under the bundled arrangement. The AMP for a quarter must be adjusted by the labeler if cumulative discounts or other arrangements subsequently adjust the prices actually realized.

Baseline Consumer Price Index-Urban (CPI-U) is the CPI-U for September, 1990. For drugs approved by FDA after October 1, 1990, "Base CPI-U" means the CPI-U for the month before the month in which the drug was first marketed.

Baseline Date AMP means the AMP for the 7/1/90 - 9/30/90 quarter for purposes of computing the AMP as of 10/1/90. For drugs approved by FDA after October 1, 1990, "Base Date AMP" means the AMP for the first day of the first month in which the drug was marketed. In order to meet this definition, the drug must have been marketed on that first day. If the drug was not marketed on that first day, "Base Date" means the AMP for the first day of the month in which the product was marketed for a full month.

Best Price means, with respect to Single Source and Innovator Multiple Source Drugs, the lowest price at which the labeler sells the covered outpatient drug to any purchaser in the United States in any pricing structure (including capitated payments), in the same quarter for which the AMP is computed. Best price includes prices to wholesalers, retailers, nonprofit entities, or governmental entities within the States (excluding Depot Prices and Single Award Contract Prices of any agency of the Federal Government). The best price shall be inclusive of cash discounts, free goods, volume discounts, and rebates, (other than rebates under Section 1927 of the Act).

Excluded from the calculation of best price are prices charged to the following entities: the Indian Health Service; the Department of Veterans Affairs; a State home receiving funds under section 1741 of title 38, United States Code; the Department of Defense; the Public Health Service (PHS) or any entity described in section 340B(a)(4) of the PHS Act and as further specified in Federal Register notices; the Federal Supply Schedule; and, a State pharmaceutical assistance program.

Bundled Sale refers to the packaging of drugs of different types where the condition of rebate or discount is that more than one drug type is purchased, or where the resulting discount or rebate is greater than that which would have been received had the drug products been purchased separately.

Consumer Price Index-Urban (CPI-U) means the index of consumer prices developed and updated by the U.S. Department of Commerce. As referenced in section 1927(c) of the Act, it is the CPI for all urban consumers (U.S. Average) and, except for the base CPI-U, it shall be the index for the month before the beginning of the calendar quarter for which the rebate is made.

Covered Outpatient Drug will have the meaning as set forth in Section 1927(k)(2), (k)(3), and (k)(4) of the Act, and with respect to the labeler includes all such drug products meeting this definition. For purposes of coverage under this agreement, all of those covered outpatient drugs are identified by the manufacturer's labeler code segment of the NDC number. Certain covered outpatient drugs, such as specified by Section 1927 (d)(1)-(3) of the Act, may be restricted or excluded from Medicaid payment at State option but shall be included by the labeler for purposes of this agreement.

Depot Price means the price(s) available to any depot of the Federal Government for purchase of drugs from the labeler through the depot system of procurement.

Federal Financial Participation means the Federal share of State expenditures for services, training, and administration under an approved State Plan for medical assistance.

Individual State Agreement means an agreement between a State and a labeler authorized or approved by HCFA as meeting the requirements specified in Section 1927(a)(1) or (a)(4) of the Act. Amendments or other changes to agreements under 1927(a)(4) shall not be included in this definition unless specifically accepted by HCFA.

An existing agreement that met these requirements as of the date of enactment of P.L. No. 101-508 (November 5, 1990), can be modified to give a greater rebate percentage.

Innovator Multiple Source Drug will have the meaning set forth in Section 1927(k)(7)(A)(ii) of the Act and shall include all covered outpatient drugs approved under a New Drug Application (NDA), Product License Approval (PLA), Establishment License Approval (ELA), or Antibiotic Drug (ADA) Approval. A covered outpatient drug marketed by a cross-licensed producer or distributor under the approved NDA shall be included as an innovator multiple source drug when the drug product meets this definition.

Labeler will have the meaning set forth in Section 1927(k)(5) of the Act except, for purposes of this agreement, it shall also mean the entity holding legal title to or possession of the NDC number for the covered outpatient drug.

Marketed means that a drug was first sold by a labeler in the States after FDA approval.

Medicaid Utilization Information means the information on the total number of units of each dosage form and strength of the labeler's covered outpatient drugs reimbursed during a quarter under a Medicaid State Plan. This information is based on claims paid by the State Medicaid agency during a calendar quarter and not drugs that were dispensed during a calendar quarter (except it shall not include drugs dispensed prior to January 1, 1991). The Medicaid utilization information to be supplied includes: 1) NDC number; 2) Product name; 3) Units paid for during the quarter by NDC number; 4) Total number of prescriptions paid for during the quarter by NDC number; and 5) Total amount paid during the quarter by NDC number. A State may, at its option, compute the total rebate anticipated, based on its own records, but it shall remain the responsibility of the labeler to correctly calculate the rebate amount based on its correct determination of AMP and, where applicable, best price.

National Drug Code is the identifying drug number maintained by the Food and Drug Administration. For the purposes of this agreement the complete 11 digit NDC number will be used including labeler code (which is assigned by the FDA and identifies the establishment), product code (which identifies the specific product or formulation), and package size code. For the purposes of making rebate payments, labelers must accept the NDC number without package size code from States that do not maintain their records by complete NDC number.

Net Sales means quarterly gross sales revenue less cash discounts allowed and all other price reductions (other than rebates under section 1927 of the Act) which reduce the actual price paid; and as further defined under the definition of AMP.

New Drug means a covered outpatient drug approved as a new drug under section 201(p) of the Federal Food, Drug, and Cosmetic Act.

New Drug Coverage begins with the date of FDA approval of the NDA, PLA, ELA or ADA, for a period of six months from that date, with the exception of drugs not under the rebate agreement or classes of drugs States elect to exclude.

Nominal Price for purposes of excluding prices from the best price calculation, means any price less than 10% of the AMP in the same quarter for which the AMP is computed.

Non-innovator Multiple Source Drug shall have the meaning as set forth in section 1927(k)(7)(A)(iii) of the Act. It also includes covered outpatient drugs approved under an ANDA or AADA.

Quarter means calendar quarter unless otherwise specified.

Rebate Payment means, with respect to the labeler's covered outpatient drugs, the quarterly payment by the labeler to the State Medicaid agency, calculated in accordance with section 1927 of the Act and the provisions of this agreement. The terms "Base CPI-U" and "Base Date AMP" will be applicable to the calculations under section 1927(c).

Rebate Per Unit (See Unit Rebate Amount)

Secretary means the Secretary of the United States Department of Health and Human Services, or any successor thereto, or any officer or employee of the Department of Health and Human Services or successor agency to whom the authority to implement this agreement has been delegated.

Single-Award Contract means a contract between the Federal Government and a labeler resulting in a single supplier for a covered outpatient drug within a class of drugs. The Federal Supply Schedule is not included in this definition as a single-award contract.

Single-Award Contract Price means a price established under a Single-Award Contract.

Single Source Drug will have the meaning set forth in section 1927(k)(7)(A)(iv) of the Act. It also includes a covered outpatient drug approved under a PLA, ELA or ABA.

States means the 50 States and the District of Columbia.

State Medicaid Agency means the agency designated by a State under section 1902(a)(5) of the Act to administer or supervise the administration of the Medicaid program.

Unit means drug unit in the lowest identifiable amount (e.g., tablet or capsule for solid dosage forms, milliliter for liquid forms, gram for ointments or creams). The labeler will specify the unit associated with each covered outpatient drug, as part of the submission of data, in accordance with the Secretary's instructions.

Unit Rebate Amount means the unit amount computed by the Health Care Financing Administration to which the Medicaid utilization information may be applied by States in invoicing the labeler for the rebate payment due. This term is synonymous with the term Rebate Per Unit, as used by the States and labelers.

ACRONYMS

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PROGRAM ACRONYMS

The acronyms listed below may not necessarily appear in this guide. However, they are used within the Medicaid Drug Rebate Program and, therefore, provided for your convenience.

(the) ACT	- The Social Security Act
AMP	- Average Manufacturer's Price
ANDA	- Abbreviated New Drug Application
BL	- Baseline
BP	- Best Price
CPI-U	- Consumer Price Index-Urban
DESI	- Drug Efficacy Study Implementation
FDA	- Food and Drug Administration
FFP	- Federal Financial Participation
HCFA	- Health Care Financing Administration
HMO	- Health Maintenance Organization
IRS	- Identical, Related, and Similar
LTE	- Less Than Effective
MCO	- Managed Care Organization
MDRI	- Medicaid Drug Rebate Initiative
NDA	- New Drug Application
NDC	- National Drug Code
NOOH	- Notice of Opportunity for Hearing
OBRA	- Omnibus Budget Reconciliation Act
OMB	- Office of Management and Budget
OTC	- Over the Counter
PBM	- Pharmacy Benefit Manager
PPA	- Prior Period Adjustment
PQAS	- Prior Quarter Adjustment Statement
RAR	- Remittance Advice Report
ROSI	- Reconciliation of State Invoice
RPU	- Rebate Per Unit (Synonymous with URA)
UPPS	- Units Per Package Size
URA	- Unit Rebate Amount (Synonymous with RPU)
VHCA	- Veterans Health Care Act

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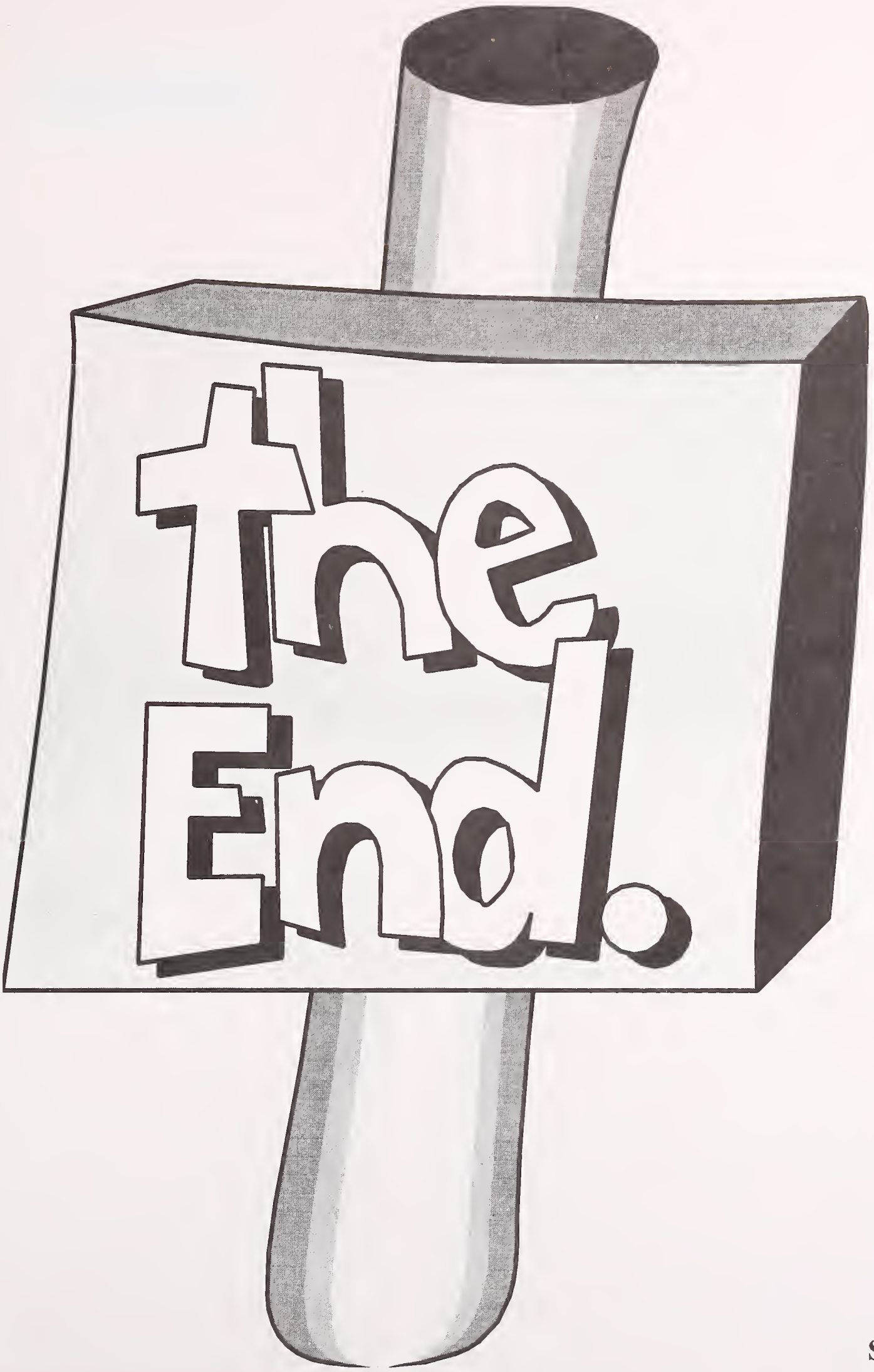
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